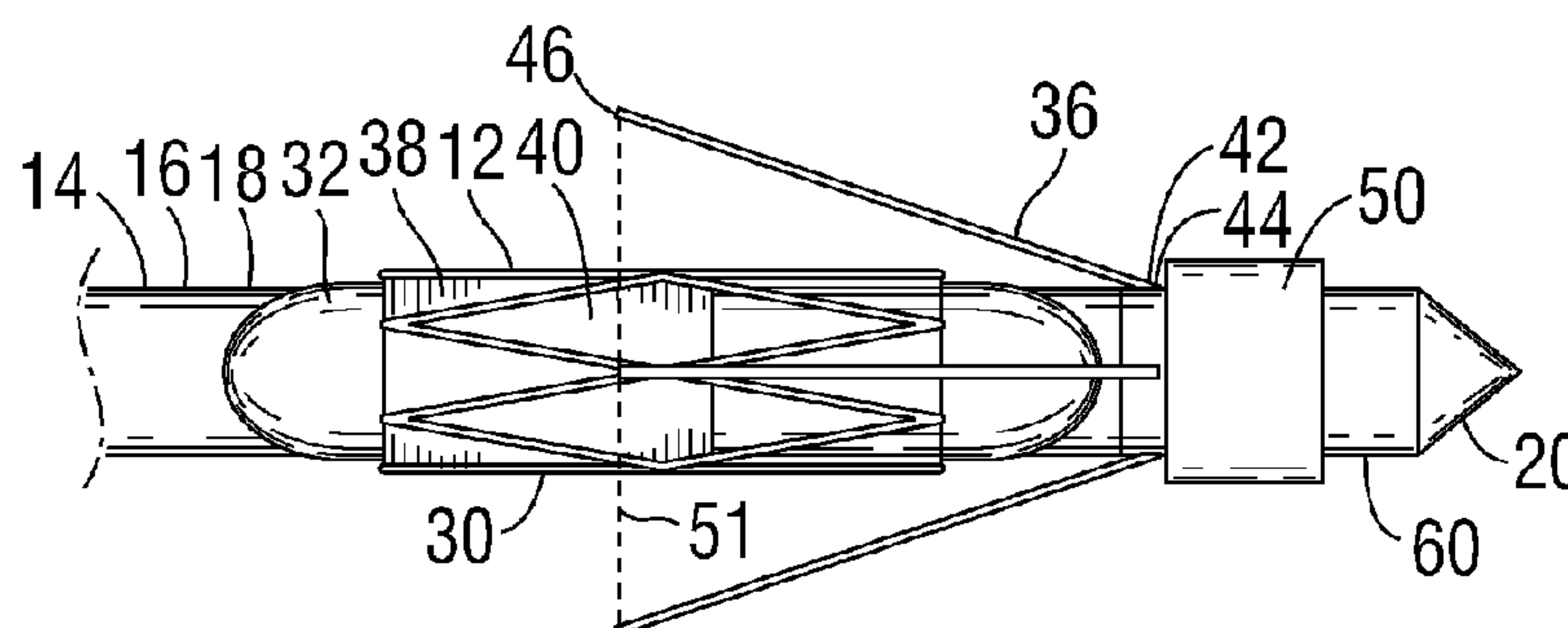




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 (72) Inventeurs/Inventors:  
 DUHAY, FRANCIS G., US;  
 ZOLLINGER, DAVID L., US  
 (73) Propriétaire/Owner:  
 EDWARDS LIFESCIENCES CORPORATION, US  
 (74) Agent: STIKEMAN ELLIOTT S.E.N.C.R.L.,SRL/LLP

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(57) **Abrégé/Abstract:**

The invention is a system and method for accurately positioning a prosthetic valve such as a prosthetic heart valve at a desired position for deployment. The invention includes extendable positioning elements which provide tactile feedback to a user to confirm proper positioning of the catheter with respect to the native valve annulus. During delivery, the extendable positioning elements lie against the catheter, over the prosthetic valve and expandable balloon, providing a low profile for advancing the catheter to the desired treatment location via small passages such as body lumens. Prior to valve deployment, the positioning elements are extended and brought into contact with tissue of the native annulus to confirm the proper positioning of the delivery system and prosthetic valve.

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(71) Applicant: EDWARDS LIFESCIENCES CORPORATION [US/US]; One Edwards Way, Legal Department, Irvine, CA 92614 (US).

## (72) Inventors; and

(75) Inventors/Applicants (for US only): DUHAY, Francis, G. [US/US]; Edwards Lifesciences, One Edwards Way, Legal Department, Irvine, CA 92614 (US). ZOLLINGER, David, L. [US/US]; Edwards Lifesciences, One Edwards Way, Legal Department, Irvine, CA 92614 (US).

(74) Agents: KAISER, Annemarie et al.; Edwards Lifesciences, One Edwards Way, Irvine, CA 92614 (US).

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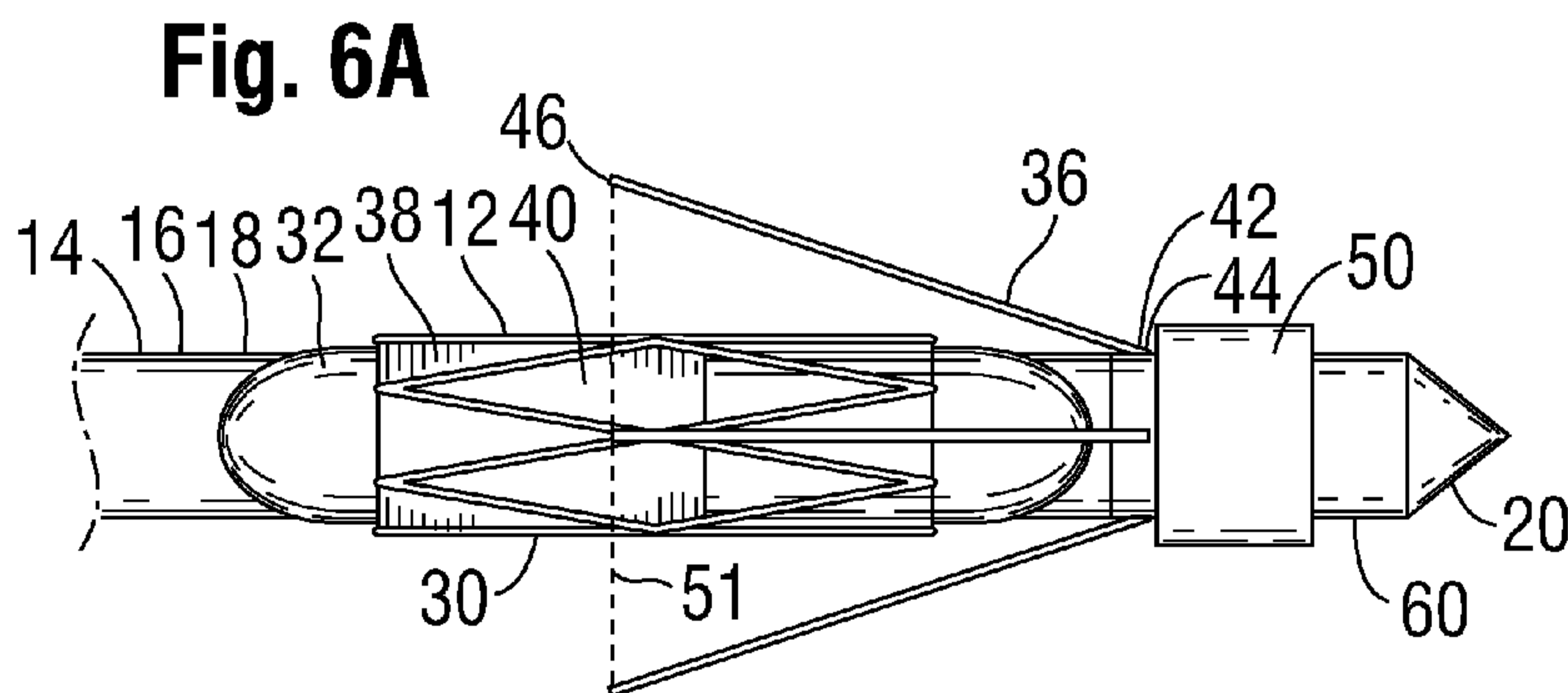
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(54) Title: DEVICES, SYSTEMS AND METHODS FOR ACCURATE POSITIONING OF A PROSTHETIC VALVE



(57) Abstract: The invention is a system and method for accurately positioning a prosthetic valve such as a prosthetic heart valve at a desired position for deployment. The invention includes extendable positioning elements which provide tactile feedback to a user to confirm proper positioning of the catheter with respect to the native valve annulus. During delivery, the extendable positioning elements lie against the catheter, over the prosthetic valve and expandable balloon, providing a low profile for advancing the catheter to the desired treatment location via small passages such as body lumens. Prior to valve deployment, the positioning elements are extended and brought into contact with tissue of the native annulus to confirm the proper positioning of the delivery system and prosthetic valve.



WO 2012/145167 A3

DEVICES, SYSTEMS AND METHODS FOR ACCURATE POSITIONING OF A  
PROSTHETIC VALVE

FIELD OF THE INVENTION

[0001] The present invention relates to methods and devices for delivering a valve prosthesis for implantation in body channels, including, but not limited to, a cardiac valve prosthesis to be implanted by surgical procedures such as open surgery, percutaneous procedures such as transcatheterization, and endoscopic minimally invasive surgery. The valve prosthesis can be also applied to other body channels provided with native valves, such as veins or in organs (liver, intestine, urethra, etc.).

BACKGROUND OF THE INVENTION

[0002] The present invention relates to systems used to deliver a prosthetic valve to a heart. More specifically, the present invention is directed to an improved delivery system for delivery of a prosthetic valve to a human heart.

[0003] Catheters for prosthetic heart valve implantation are known in the art and have been commonly used to reach locations inside the body that are not readily accessible by surgery or where access without surgery is desirable. Numerous transcatheter techniques are known in the art, including techniques which are percutaneous, trans-arterial, trans-venous, trans-cardiac, trans-atrial, trans-ventricular, and/or trans-apical. A key factor in such transcatheter heart valve deployment is properly positioning the prosthetic implant, e.g., accurately positioning a prosthetic heart valve within the native heart valve annulus.

[0004] Over the years, a variety of techniques have been proposed and/or used for facilitating proper positioning of catheters. For example, current transcatheter valve implantation systems, such as the Edwards SAPIEN<sup>TM</sup> Transcatheter Heart Valve, use fluoroscopy and/or echography to properly position the valve within the native valve annulus prior to deployment. Such imaging modalities involve extensive and complicated equipment, and may also have limitations in their accuracy in some circumstances. Improvements may be desired which, when compared to known techniques, may provide improved accuracy, reduced cost/complexity, and/or backup positioning (when used in combination with known techniques).

[0005] Prior art methods also include modifications to the implant itself. For example, some transcatheter valve implantation systems employ retractable metal positioners that extend from the valve frame. For example, US Patent Nos. 7,201,772 and 7,399,315, as well as US Patent No. 8,348,996, disclose the use of positioners which are an integral component of the prosthetic heart valve frame. The positioners add extra material to the prosthetic heart valve. Also, upon deployment of the prosthetic heart valve in the patient, the positioners remained in the patient.

[0006] Another approach includes the filling (via injection, etc.) of a portion of the prosthetic implant itself with a radiographic contrast solution. After the surgeon or other user has properly positioned and deployed the implant, the radiographic contrast solution is pumped out and replaced with a hardening agent which increases the stiffness of the implant in order to aid in retaining the implant at the desired position. Such a technique is relatively complex.

[0007] Although a variety of prosthetic valve positioning methods and systems have been proposed over the years, each of the existing methods and systems has shortcomings. Additionally, improved methods and systems may be used in combination with previously-known methods in order to achieve improved accuracy and/or reliability. Accordingly, an urgent need exists for an improved valve positioning method and system which is versatile, reliable, and easy to use. The present invention addresses this need.

#### SUMMARY OF THE INVENTION

[0008] Preferred embodiments of the present invention provide a heart valve delivery system for delivery of a prosthetic (i.e., replacement) heart valve to a native valve site within the human vasculature. The delivery system includes a delivery catheter having one or more extendable positioning limbs configured to be selectively and radially extended from the catheter body.

[0009] In an exemplary embodiment of the invention, positioning elements are incorporated into the valve delivery catheter itself. The positioning elements may be configured to be radially expanded and/or longitudinally displaced with respect to other elements of the valve delivery catheter.

[0010] In one exemplary embodiment of the invention, a prosthetic heart valve is positioned on a distal portion of a delivery catheter. One or more extendable limbs are also

positioned on the delivery catheter. Each extendable limb extends from a fixed end to a free end, with the fixed end secured to the delivery catheter. The fixed end is secured to the delivery catheter at a position which is longitudinally displaced from the prosthetic heart valve, with the free end positioned longitudinally adjacent the prosthetic heart valve, such that the extendable limb extends over at least a portion of the length of the prosthetic heart valve. The extendable limb is configured to transform from a restrained position wherein the free end is positioned tightly against the catheter body to an extended position wherein the free end is radially extended away from the catheter body.

[0011] The extendable limbs may be spring-loaded or otherwise configured such that, when the limb is radially unrestrained, the free ends thereof will revert to a position wherein the free ends are radially extended away from the catheter body. For example, the extendable limbs may be formed from a memory material.

[0012] A sliding cuff may be used to restrain the extendable limbs. The sliding cuff may be configured to slide over the extendable limbs starting from a position adjacent the fixed ends of the extendable limbs, with the sliding cuff configured to be slid over the extendable limbs in a direction toward the free ends thereof. The sliding cuff may have an internal diameter sized to permit the sliding cuff to be slid over the catheter and extendable limbs in a relatively tight fashion, such that as the sliding cuff is slid over the extendable limbs the limbs are forced to assume their restrained position wherein the free ends thereof are positioned radially against the catheter.

[0013] In one example of a method according to the invention, a prosthetic heart valve is configured for deployment using a balloon. For example, the prosthetic heart valve may comprise a balloon expandable stent supporting a bioprosthetic valve. A delivery catheter may include an expandable balloon at a distal portion of the catheter. Prior to implantation, the prosthetic heart valve is carefully crimped onto the balloon of the delivery catheter of the invention. The positioners, in the form of retractable members, are positioned at least partially over and tightly against the prosthetic valve, such that the overall profile of the catheter distal portion (with expandable balloon, prosthetic valve, and positioners) is relatively low in order to promote easy advancement of the catheter through the body lumen(s). The catheter distal portion (with prosthetic valve thereon) can then be advanced to the desired position for valve deployment. For example, for replacing an aortic valve, the catheter distal portion may be advanced into the patient via the femoral artery and delivered

to a native stenotic aortic valve using a retrograde approach, or may be advanced into the patient via an intercostal or other chest opening and into the left ventricular apex to the native stenotic aortic valve using an antegrade approach.

[0014] Once the catheter distal portion with prosthetic valve thereon is positioned at the native valve annulus, the positioners are used to refine the positioning. In one embodiment of the invention, the catheter distal portion is advanced distally until the prosthetic heart valve passes through the native valve annulus. The retractable members are then radially deployed away from the catheter. The catheter distal portion is then retracted proximally at least partially back through the native valve annulus until the retractable members engage against the native valve leaflets, valve annulus, and/or other structures. The user then knows that the prosthetic heart valve is at the desired position. The user can then deploy the prosthetic heart valve at the desired position within the native valve annulus. In one embodiment of the invention, the retractable members are pressed between the prosthetic heart valve and native valve annulus when the prosthetic heart valve is deployed. In such an embodiment, after the prosthetic heart valve is properly deployed the catheter distal portion can be advanced once again distally a distance sufficient for the retractable members to slip free of the deployed prosthetic heart valve and native valve annulus. The retractable members are then radially retracted against the catheter distal portion (i.e., to their retracted/delivery state), and the entire catheter assembly can be withdrawn from the heart valve, heart, and patient, leaving the prosthetic valve in proper placement in the heart.

[0015] In one embodiment of the invention, after the accurate positioning the catheter within the valve annulus using the retractable member, but prior to actual deployment of the prosthetic heart valve, the retractable members are advanced distally away from the prosthetic heart valve. This advancement of the retractable members occurs while the rest of the catheter remains stationary, i.e., with the prosthetic heart valve held in the desired position for deployment as described above. To distally advance the retractable members while holding the catheter stationary requires the retractable members to be configured for distal displacement with respect to the rest of the catheter, including the portion to which the prosthetic heart valve is secured. For example, the retractable members may be secured to a sliding assembly which permits the retractable members to be distally advanced with respect to the expandable balloon and/or other structures to which the prosthetic heart valve is held on the catheter. In such an embodiment, after the retractable members are advanced distally

(but with the prosthetic heart valve still at the selected and accurate deployment position), valve is properly deployed (e.g., by expanding a valve deployment balloon). The retractable members can be radially retracted just before, during, or just after deployment of the prosthetic valve. After the valve is deployed, and with the retractable members radially retracted to their retracted position, the entire catheter assembly can be withdrawn from the heart valve, heart, and patient, leaving the prosthetic valve in proper placement in the heart.

[0016] The system is well suited for advancing a prosthetic valve into the heart via one or more blood vessels such as the aorta and/or femoral artery, preferably with the retractable members retracted during advancement through the aorta and/or femoral artery and/or other body lumen, but with the retractable members then extended when the system has advanced the prosthetic heart valve to a position at or adjacent the native valve annulus. The system is also well suited for advancing a prosthetic valve into the heart via a surgically-created opening in the heart wall such as an apical puncture, preferably with the retractable members retracted during advancement through the apical puncture, but with the retractable members then extended when the system has advanced the prosthetic heart valve to a position at or adjacent the native valve annulus.

[0017] The catheter with prosthetic heart valve and retractable members may be advanced into the heart from a position upstream or downstream of the native heart valve being replaced. The retractable members may be advanced in an expanded configuration toward the native heart valve annulus from a position upstream or downstream of the native heart valve.

[0018] A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Features and advantages of the present invention will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

[0020] FIG. 1 is a perspective view of a system for replacing a deficient valve according to an embodiment of the invention;

[0021] FIGS. 2A-2B depict side and distal end views, respectively, of a distal portion of the system of FIG. 1, with the system in the delivery configuration, according to an embodiment of the invention;

[0022] FIGS. 3A-3B depict side and distal end views, respectively, of the system of FIGS. 2A-2B, with the positioning members extended;

[0023] FIGS. 4A-4B depict side and distal end views, respectively, of the system of FIGS. 2A-2B, with the balloon expanded to deploy the prosthetic valve;

[0024] FIG. 5 depicts a side view of a distal portion of a system for replacing a deficient valve, with the positioning members fully extended, according to an embodiment of the invention;

[0025] FIG. 6A depicts a side view of a distal portion of a system for replacing a deficient valve according to an embodiment of the invention;

[0026] FIG. 6B depicts a side view of the system of FIG. 6A, with a distal end portion of the device extended telescopically from rest of the distal portion;

[0027] FIGS. 7A-7B depict side views of a distal portion of a system for replacing a deficient valve according to an embodiment of the invention;

[0028] FIGS. 8A-8B depict side views, respectively, of a distal portion of a system for replacing a deficient valve according to an embodiment of the invention;

[0029] FIGS. 9A-9B depict cross-sectional views through the left side of a patient's heart showing a prosthetic valve being delivered and deployed to a native valve annulus via a retrograde approach according to an embodiment of the invention;

[0030] FIGS. 10A-10B depict cross-sectional views through the left side of a patient's heart showing a prosthetic valve being delivered and deployed to a native valve annulus via an antegrade transapical approach according to an embodiment of the invention;

[0031] FIGS. 11A-11B depict cross-sectional views through the left side of a patient's heart showing a prosthetic valve being delivered and deployed to a native valve annulus via a retrograde approach according to an embodiment of the invention;

[0032] FIGS. 12A-12B depict cross-sectional views through the left side of a patient's heart showing a prosthetic valve being delivered and deployed to a native valve annulus via an antegrade transapical approach according to an embodiment of the invention; and

[0033] FIGS. 13A-13B depict side (in partial cross-section) and distal end views, respectively, of a distal portion of a device according to an embodiment of the invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0034] FIG. 1 depicts a delivery system 10 configured to deliver a prosthetic implant such as a prosthetic valve 12 to a selected position using a delivery catheter 14. The delivery catheter 14 comprises a generally elongated catheter main body 16. A catheter distal portion 18 terminates at a catheter distal end 20, and a catheter proximal portion 22 terminates in a catheter proximal end 24. The catheter proximal portion 22 includes a catheter handle 26 which may have one or more controls 27, 28, 29.

[0035] The catheter main body 16 may have a usable length (i.e., from the distal end of the handle 26 to the catheter distal end 20) sufficient to permit a user to advance the catheter distal portion 18 with prosthetic valve 12 thereon to a desired position within the patient while the catheter handle 26 remains accessible to the user at a position outside of the patient. For a catheter for delivering a heart valve via a transfemoral approach (via the femoral artery and aorta), the catheter 14 may have a usable length sufficient to reach from an incision in the patient's leg, through the femoral artery, through the aorta, and into the aorta. For such a procedure the catheter usable length may be about 130 cm. With a catheter for delivering a heart valve via an apical approach (e.g., via an intercostal incision in the chest wall and then thru a puncture in the heart apex), the catheter may have a usable length of about 24 inches or less.

[0036] The catheter distal portion 18 includes an implant holding section 30 to which the prosthetic valve 12 is positioned. In the particular embodiment depicted, the implant holding section is a catheter balloon 32 configured to be selectively expanded to an enlarged diameter to thereby expand the prosthetic valve 12 to its enlarged/deployed diameter, whereby the prosthetic valve 12 is expanded into contact with the native valve annulus.

[0037] Note that the catheter distal portion may include a sheath configured to be slid over the prosthetic valve in its unexpanded/delivery diameter. For a self-expanding prosthetic valve (e.g., a prosthetic valve having a support stent biased to self-expand to an expanded/deployed diameter when released from a restrained/unexpanded configuration, such as a support stent formed from a memory material such as Nitinol), the sheath restrains the prosthetic valve in its unexpanded/delivery diameter. The sheath is further configured to be slid off of the prosthetic valve to release the prosthetic valve. For a self-expanding prosthetic valve, sliding the sheath off of the valve permits the support stent to self-expand to

its enlarged/deployment diameter. The sheath may be in addition to or in lieu of an expandable balloon such as that depicted in FIG. 1.

[0038] The catheter 14 further comprises a positioner 34 positioned at the catheter distal portion 18. The positioner 34 comprises one or more members 36 which can be radially extended from and/or retracted against the catheter distal end 18.

[0039] A user may control operation of the balloon 32, positioner 34, and/or sheath by movement or other activation of one or more of the controls 27, 28, 29 on the handle 26. For example, a first control 27 may control, via sliding movement thereof, extension and/or retraction of the retractable member 36 of the positioned 34. A second control 28 may control, via sliding movement, the sliding advancement/retraction of the sheath. A third control 29 may control the flow of fluid into and/or out of the balloon 32 to inflate and/or deflate the balloon 32.

[0040] FIGS. 2A-2B depict close-up views of the catheter 14 of FIG. 1, and particularly of the catheter distal portion 18. The prosthetic valve 12 comprises a support stent 38 surrounding prosthetic valve leaflets 40. The prosthetic valve 12 is tightly crimped onto the expandable balloon 32.

[0041] The retractable members 36 each have a fixed end 42 secured to the catheter distal portion 18 at a fixed end attachment point 44 which is distal of the implant holding section 30 and of the prosthetic valve 12. The retractable members 36 each have a free end 46, which may be rounded at the tip to prevent unnecessary trauma to tissue when the free end 46 is pressed against same. In the particular embodiment depicted, the retractable members 36 are in their retracted/unexpanded configuration, and extend proximally from the fixed end attachment point 44 to the free end 46. The free end 46 is positioned radially adjacent the catheter distal portion 18 at a position overlying the prosthetic valve 12 and implant holding section 30/expandable balloon 32. In the particular embodiment depicted, when in the retracted position the free end 46 is positioned longitudinally adjacent the middle third portion 47 of the prosthetic valve 12 and also of the middle third portion 49 of the expandable balloon 32 (which in the particular embodiment depict coincides with a middle third portion of the implant holding section 30), with the body of the retractable member 36 passing over a valve annulus alignment position 51 along the length of the prosthetic heart valve 12 which is intended to be aligned with structure of the valve annulus (or other target tissue) against which the member free ends will engage when positioning the device. In a

preferred embodiment of the invention, the retractable member 36 has a member length 48 from fixed end attachment point 44 to free end 46 of about 10 to 15 mm.

[0042] In the particular embodiment of FIGS. 2A-2B, the catheter 14 includes a cuff 50 configured to be slidably advanced over and with respect to the retractable members 36. In the embodiment of FIGS. 2A-2B, the cuff 50 is positioned over the retractable members 36, thus holding the retractable members 36 in their retracted/unexpanded position such that the retractable members 36 are held against and generally parallel to the catheter distal portion 18, with the free ends 46 positioned radially adjacent the prosthetic valve 12 and balloon 32.

[0043] As depicted in FIGS. 3A-3B, the cuff 50 can be slid distally, thus extending the retractable members 36 away from the catheter 14. The retractable members 36 may be spring-loaded or otherwise biased (e.g., via memory materials, etc.) toward their extended configuration, and/or may be configured to be mechanically extended to the extended configuration via other means known in the art. The free ends 46 of the retractable members 36 are positioned a radial distance 52 away from the radial center 54 of the catheter proximal portion, and are also aligned lengthwise with the alignment position 51 of the prosthetic valve 12.

[0044] In one exemplary embodiment of the invention for use with implanting a prosthetic heart valve, the radial distance 52 when the members 36 are retracted (as depicted in FIG. 2A) is about the same as, or just slightly larger than (in order to lie flat on the surface of the valve), the radius of the prosthetic valve when the valve is mounted on the catheter in its crimped/unexpanded/predeployment configuration. For example, for a prosthetic valve which in its unexpanded state has a diameter of 8 mm (i.e., a radius of 4 mm), the radial distance 52 would be about 4mm or slightly more (e.g., 5 mm). When the members 36 are extended, such as depicted in FIGS. 3A-3B, the radial distance 52 would be about the same as the radius (i.e., one-half of the diameter) of the native heart valve annulus, or slightly larger so that the free ends 46 of the retractable members 36 engage against tissue adjacent the annulus. In an exemplary embodiment, the retractable members when fully extended define a diameter of about 15 mm to 35 mm, so that the radial distance 52 is about 7 mm to 18 mm. Note that other sizes are also within the scope of the invention.

[0045] The retractable members 36 serve as guides for the user to determine if the catheter 14 is properly positioned such that the prosthetic valve 12 is properly aligned with the native valve annulus. Once the user determines that the prosthetic valve 12 is in proper

position for deployment, he/she can expand the balloon 32 to expand the support stent 38 to its expanded/deployed diameter and thereby deploy the prosthetic heart valve 12, as depicted in FIGS. 4A-4B.

[0046] The retractable members may be configured (via spring-loading, hinge connection, and/or memory materials) to assume a somewhat L-shaped and/or curved configuration when extended to their deployed configuration. For example, as depicted in FIG. 5, a catheter 14 has a retractable member 36 (which may have been generally straight from free end to fixed end when in the restrained/unexpanded condition such as in the embodiment depicted in FIGS. 2A-2B) which may include one or more bend/hinge points 56 along its length between generally straight segments 36a, 36b when in an expanded configuration. With the retractable members 36 fully extended and the balloon 32 expanded, the free-end adjacent segment 36a is generally parallel to and adjacent the expanded balloon 32 (and also generally parallel to the catheter distal portion 18), while the fixed-end adjacent segment 36b is angled sharply away from the catheter distal portion 18 to position the free-end adjacent segment 36a at the desired radial distance 52 from the radial center 54. With such a configuration, the free-end adjacent segment 36a can be pressed between the native valve annulus and prosthetic valve 12 when the balloon 32 is expanded, but without substantially interfering with the radial expansion of the prosthetic valve 12 and its support stent 38. Moreover, the free-end adjacent segment 36a, due to its generally parallel orientation, can also be somewhat easily slid out from between the native valve annulus and deployed prosthetic valve 12.

[0047] A catheter according to the invention may comprise materials to enhance visibility with various medical imaging techniques, such as fluoroscopy, ultrasound, magnetic resonance, etc. For example, the catheter 14 may include one or more markers for enhanced visibility, such as radiopaque markers, at various positions. In a preferred embodiment, radiopaque markers 58 are included at the free ends 46 of the retractable members 36, as depicted in FIG. 5. The radiopaque markers 58, which are more radiopaque than other portions of the catheter assembly, may assist the user to more clearly see exactly where the retractable members 36 and their associated free ends 46 are positioned. The user can also use the radiopaque marker 58 to visually confirm that the retractable members 36 are radially expanded.

[0048] In another embodiment of the invention, depicted in FIGS. 6A-6B, the catheter 14 includes a slidingly-movable portion 60 which includes the fixed end attachment point 44 to which the fixed end 42 of the retractable member 36 is secured. The slidingly-movable portion 60 can be advanced distally away from (for an embodiment such as depicted in FIGS. 2A-4B) or proximally away from (for an embodiment such as depicted in FIGS. 7A-8B) the implant holding section 30 and/or balloon 32 without requiring movement of the rest of the catheter 32. In a method of using such an embodiment, the user can extend the retractable member(s) 36 to an expanded/deployed position, depicted in FIG. 6A, and use the deployed member(s) 36 to properly position the implant holding section 30 and/or balloon 32 (with prosthetic valve 12 thereon) at the desired deployment location. Once the desired deployment location is achieved, the catheter 12 can be held stationary to keep the (still undeployed) prosthetic valve 12 at the desired deployment location, while the slidingly-movable portion 60 is slid away, via a longitudinally extendable support rod 62, from implant holding section 30 and/or balloon 32 (with prosthetic valve 12 thereon) until the retractable members 36 are largely or entirely clear, with respect to the length of the catheter 12, of the implant holding section 30 and/or balloon 32 (with prosthetic valve 12 thereon), as depicted in FIG. 6B. The prosthetic valve 12 is deployed to its expanded configuration, e.g., by expanding the balloon 32. Note that the expanded balloon 32 and prosthetic valve 12 are clear of the retractable members 36 and the free ends 46 thereof. Before, during, or after deployment of the prosthetic valve 12 and/or expansion of the balloon 32, the retractable members 36 can be retracted to their unexpanded/delivery figuration. With the prosthetic valve 12 deployed, the balloon 32 can be deflated, and the catheter 12 (with deflated balloon and retracted retractable members) can be withdrawn from the patient through the now-deployed prosthetic valve 12.

[0049] In the embodiments depicted above, the retractable members were secured with their fixed ends distal of the implant holding section. In other embodiments, however, such as those depicted in FIGS. 7A-7B, the retractable members 36 are secured with their fixed ends 42 secured to the catheter distal portion 18 at fixed end attachments points 44 which are proximal of the implant holding section 30, balloon 32, and prosthetic valve 12. When in a retracted configuration (i.e., delivery and/or removal configuration) such as that depicted in FIG. 7A, the free end 46 is positioned radially adjacent the catheter distal portion 18 at a position overlying the prosthetic valve 12 and implant holding section 30/expandable balloon

32. In the particular embodiment depicted, the free end 46 is also positioned longitudinally adjacent the middle third portion 47 of the prosthetic valve 12 and also of the middle third portion 49 of the expandable balloon 32 (which in the particular embodiment depict coincides with a middle third portion of the implant holding section 30). When the retractable members 36 are deployed to the larger deployed configuration, the free ends 46 are in longitudinal alignment with the tissue alignment position 51 of the prosthetic valve.

[0050] While the above embodiments have depicted an implant such as a prosthetic valve being deployed using a balloon catheter, other deployment methods and devices are also within the scope of the invention. For example, a prosthetic valve 12 or other implant may be a self-expanding device restrained by a sheath 70 configured to be slid over all or a portion of the implant holding section 30 to restrain the prosthetic valve 12 therein, as depicted in FIG. 8A, for delivery of the prosthetic valve 12 to the treatment site. The retractable members 36 can be extended to assist in accurately positioning the prosthetic valve 12, and the sheath 70 can then be slidingly retracted from the implant holding section to release the prosthetic valve 12, which then self-expands, as depicted in FIG. 8B. The self-expanding support structure 38 of the prosthetic valve 12 thus expands into contact with the native valve annulus.

[0051] FIGS. 9A-9B depict a catheter 14 (similar to that depicted in FIGS. 2A-2B) delivering a prosthetic valve 12 into a heart 80 for deployment within the native valve annulus 82 via a retrograde approach according to an embodiment of the invention. The catheter 14 is advanced into the patient via the femoral artery (not shown) and then through the aorta 84 and aortic sinus 88, through the native valve annulus 82 and native valve leaflets 86, and into the left ventricle 90. Once the free ends 46 of the retractable members 36 have cleared the valve annulus 82, as depicted in FIG. 9A, the retractable members 36 can be deployed/radially extended. The user can then slowly retract the catheter 14 until the free ends 46 contact the native valve annulus 82, native valve leaflets 86, and/or other valve or valve-adjacent tissue, as depicted in FIG. 9B. Using tactile feedback from the catheter 14 created by the contact of the free ends 36 with the valve tissue and/or valve-adjacent tissue, the user can confirm the proper positioning of the prosthetic valve 12. With the proper positioning confirmed, the user can expand the balloon 32 or otherwise (e.g., via removal of a restraining sheath, etc.) effectuate expansion/deployment of the prosthetic valve 12 into the desired position within the native valve annulus 82. The retractable members 36 are retracted

back to their restrained/unexpanded configuration, the balloon 32 is deflated to a reduced diameter, and the catheter 14 is then withdrawn from the heart, leaving the prosthetic valve deployed within the heart.

[0052] Note that the user may rely on additional positioning techniques, such as fluoroscopy, echocardiography, etc. For example, during initial advancement of the catheter into the heart, the user may use fluoroscopic, echocardiographic, and/or other imaging methods to provide visual confirmation of the orientation and position of the catheter, prosthetic valve, and/or positioning elements relative to the native valve annulus or other deployment site. The user may also use the fluoroscopic, echocardiographic, and/or other imaging methods to provide visual confirmation of the orientation and position of various elements of the delivery system in addition to the tactile feedback provided by the positioning elements, e.g., during the positioning of the device described herein using the positioning elements. The tactile feedback thus provides the operator with another important sensory cue to the relative position of the positioning elements/prosthetic valve with respect to the native valve annulus.

[0053] While the specific methods discussed above address replacement of an aortic valve, the invention can be used to aid in the accurate positioning and deployment of implants relative to all cardiac valves, as well as relative to other orifices and body lumens, such as the orifices of all the major arteries and veins related to the heart (including but not limited to the superior and inferior vena cavae, pulmonary arteries and veins, coronary sinus, innominate artery, common carotid arteries, and subclavian arteries).

[0054] FIGS. 10A-10B depict a catheter 14 (similar to that depicted in FIGS. 2A-2B) delivering a prosthetic valve 12 into a heart 80 for deployment within the native valve annulus 82 via an antegrade approach according to an embodiment of the invention. The catheter 14 is advanced into the patient via an intercostal incision (not shown) and then through a puncture 92 in the apex 94 of the heart 80 and into the left ventricle 90. The catheter 14 is then advanced through the native valve annulus 82 and native valve leaflets 86, and into the aortic sinus 88 and aorta 84. Once the free ends 46 of the retractable members 36 have cleared the valve annulus 82, as depicted in FIG. 10A, the retractable members 36 can be deployed/radially extended. The user can then slowly retract the catheter 14 until the free ends 46 contact the native valve annulus 82, native valve leaflets 86, and/or other valve or valve-adjacent tissue, as depicted in FIG. 10B. Using tactile feedback from the catheter 14

created by the contact of the free ends 36 with the valve tissue and/or valve-adjacent tissue, the user can confirm the proper positioning of the prosthetic valve 12. With the proper positioning confirmed, the user can expand the balloon 32 or otherwise (e.g., via removal of a restraining sheath, etc.) effectuate expansion/deployment of the prosthetic valve 12 into the desired position within the native valve annulus 82. The retractable members 36 are retracted back to their restrained/unexpanded configuration, the balloon 32 is deflated to a reduced diameter, and the catheter 14 is then withdrawn from the heart, leaving the prosthetic valve deployed within the heart. The apical puncture 92, intercostal incision, and other incisions are closed (e.g., via suturing) to complete the procedure.

[0055] FIGS. 11A-11B depict a catheter 14 (similar to that depicted in FIGS. 7A-8B) delivering a prosthetic valve 12 into a heart 80 for deployment within the native valve annulus 82 via a retrograde approach according to an embodiment of the invention. The catheter 14 is advanced into the patient via the femoral artery (not shown) and then through the aorta 84 to a position where the retractable members 36 are in the coronary sinus 88 and just short of the native valve annulus 82 and native valve leaflets 86. The distal end 18 of the catheter 14 may be positioned just short of, within, or through the native valve annulus 82. The retractable members 36 (which extend with the free ends 36 thereof facing distally with respect to the catheter 12) are then deployed/radially extended, as depicted in FIG. 11A. The user can then slowly advance the catheter 14 until the free ends 46 contact the native valve annulus 82, native valve leaflets 86, and/or other valve or valve-adjacent tissue, as depicted in FIG. 11B. Using tactile feedback from the catheter 14 created by the contact of the free ends 36 with the valve tissue and/or valve-adjacent tissue, the user can confirm the proper positioning of the prosthetic valve 12. With the proper positioning confirmed, the user can expand the balloon 32 or otherwise (e.g., via removal of a restraining sheath, etc.) effectuate expansion/deployment of the prosthetic valve 12 into the desired position within the native valve annulus 82. The retractable members 36 are retracted back to their restrained/unexpanded configuration, the balloon 32 is deflated to a reduced diameter, and the catheter 14 is then withdrawn from the heart, leaving the prosthetic valve 12 deployed within the heart.

[0056] FIGS. 12A-12B depict a catheter 14 (similar to that depicted in FIGS. 7A-7B) delivering a prosthetic valve 12 into a heart 80 for deployment within the native valve annulus 82 via an antegrade approach according to an embodiment of the invention. The

catheter 14 is advanced into the patient via an intercostal incision (not shown) and then through a puncture 92 in the apex 94 of the heart 80 and into the left ventricle 90. The catheter 14 is then advanced toward the native valve annulus 82 and native valve leaflets 86, but stopping with the free ends 46 of the retractable members 36 just short thereof. With the free ends 46 just short of the native valve annulus 82, as depicted in FIG. 12A, the retractable members 36 can be deployed/radially extended. The user can then slowly advance the catheter 14 until the free ends 46 contact the native valve annulus 82, native valve leaflets 86, and/or other valve or valve-adjacent tissue, as depicted in FIG. 12B. Using tactile feedback from the catheter 14 created by the contact of the free ends 46 with the valve tissue and/or valve-adjacent tissue, the user can confirm the proper positioning of the prosthetic valve 12. With the proper positioning confirmed, the user can expand the balloon (not shown) or otherwise (e.g., via removal of a restraining sheath, etc.) effectuate expansion/deployment of the prosthetic valve 12 into the desired position within the native valve annulus 82. The retractable members 36 are retracted back to their restrained/unexpanded configuration, the balloon is deflated to a reduced diameter, and the catheter 14 is then withdrawn from the heart 80, leaving the prosthetic valve 12 deployed within the native valve annulus 82. The apical puncture 92, intercostal incision, and other incisions are closed (e.g., via suturing) to complete the procedure.

[0057] Other devices and methods are also within the scope of the invention, as well is the use of various materials to form aspects thereof. For example, the retractable members may be formed from materials such as metal and/or plastic. The retractable members may be attached to the delivery catheter through an inner lumen, with a control line passing through the inner lumen back to the handle and to the retractable member controls. The number of retractable members extending from the catheter may range from 1 to 16 or more. The retractable members may be equally spaced about the circumference of the catheter body. The retractable members may be spring-loaded or otherwise biased toward an expanded configuration, such that releasing them from a restrained configuration (such as by withdrawing a restraining sheath, or advancing the members out of a lumen) results in deployment of the retractable members radially outward from the catheter body. The retractable members may be inflatable, wherein when uninflated they lie generally flat against the catheter but when inflated they assume their expanded/deployed configuration with the free ends displaced radially away from the catheter body. The retractable members

may be deployed and/or retracted using a combination of the above-discussed methods. For example, member deployment could be achieved via spring-loading and/or memory aspects of the member material, while member retraction could be achieved by retracting the members into a restraining sheath.

[0058] The retractable members may have rounded free ends to prevent tissue trauma from contact with the free ends. For example, the retractable members may be looped structures, similar in form to a wire kitchen whisk, forming smooth, rounded contact surfaces on the free ends of each retractable member.

[0059] In a further embodiment depicted in FIGS. 13A-13B, the retractable members 36 of a catheter 14 may all be interconnected, or tethered, to each other via one or more tethers 100, 102, so that when the retractable members 36 are expanded the resulting contact surface 104 presented to the native valve annulus (or other tissue) by the tether 102 connecting the free ends 46 is a smooth, circular surface. The overall structure created by the deployed retractable members 36 and tethers 100, 102 would thus resemble a cone, such as a badminton shuttlecock, along a central axis coinciding with a central axis of the catheter. One or more of the tethers, and particularly the tether 102 between the free ends 46, may each form a continuous, hollow, and inflatable space 106 which can hold a fluid. When the inflatable tether ring 102 is inflated with a fluid solution, the free ends 46 are prevented from contacting the tissue of the valve annulus (or other tissue) and instead all tissue contact is with the inflatable ring 102, which presents a smooth, atraumatic contact surface 104 to reduce local trauma. The fluid solution may comprise a radiographic contrast solution to permit enhanced fluoroscopic visualization.

[0060] While in the detailed descriptions above the systems and methods is described for replacing a native valve, the systems and methods of the invention could also be used to replace previously-deployed prosthetic devices, such as a previously-deployed prosthetic heart valve which was failing due to structural and/or other failure/damage.

[0061] While the invention has been described in various embodiments, it is to be understood that the words which have been used are words of description and not of limitation. Therefore, changes may be made within the appended claims without departing from the true scope of the invention.

What is claimed is:

1. A catheter for delivering a prosthetic heart valve to a position within a patient, comprising: a catheter proximal portion ending in a catheter proximal end; a catheter distal portion ending in a catheter distal end, the catheter distal portion having an implant holding section configured to receive the prosthetic heart valve thereon; the prosthetic heart valve positioned at the implant holding section, the prosthetic heart valve comprising a valve portion and a support portion, wherein the support portion is configured to support the valve portion and secure the valve portion in or adjacent a native valve annulus, wherein the support portion is the only structure configured to secure the valve portion in or adjacent the native valve annulus; a catheter length from the catheter proximal end to the catheter distal end, wherein the catheter length is sufficient to reach from a position outside of a patient's body to a position at a native valve annulus within the patient's body; and at least one extendable positioner configured to be selectively and radially extended from a first position to a second position, wherein in the first position the extendable positioner is positioned generally parallel to and against the catheter distal portion with the extendable positioner extending at least partially over the implant holding section, wherein in the second position at least a portion of the extendable positioner extends radially away from the catheter distal portion, wherein in the second position a portion of the extendable positioner extends longitudinally over but radially displaced away from and outside of the valve portion and the support portion of the prosthetic heart valve; wherein the prosthetic heart valve is configured to be radially expanded and released from the catheter, and the extendable positioner is configured so that after the prosthetic heart valve is released from the catheter and deployed in the native valve annulus, the entirety of the extendable positioner remains secured to the catheter and is configured to be withdrawn in its entirety from the body with the catheter.
2. The catheter of claim 1, wherein the extendable positioner comprises a positioner fixed end secured to the catheter distal portion and a positioner free end, wherein in the first position the positioner fixed end is secured to and adjacent the catheter distal portion while the positioner free end is radially adjacent the catheter distal portion, wherein in the second position the positioner fixed end is secured to and adjacent the

catheter distal portion while the positioner free end is extended radially away from the catheter distal portion.

3. The catheter of claim 2, wherein the catheter distal portion comprises a radial center, and wherein in the first position the positioner free end is positioned radially away from the radial center by a radial distance of about 2 to 5 mm.
4. The catheter of claim 2, wherein the catheter distal portion comprises a radial center, and wherein in the second position the positioner free end is positioned radially away from the radial center by a distance of about 7 to 18 mm.
5. The catheter of claim 2, wherein in the second position the positioner free end is positioned longitudinally aligned with a middle third portion of the implant holding section.
6. The catheter of claim 5, wherein the catheter distal portion comprises a sheath positioned over the implant holding section, wherein the sheath is configured to be slidingly retracted from the implant holding section, and wherein the catheter proximal portion comprises a valve deployment control configured to selectively and slidingly retract the sheath from the implant holding section, wherein the catheter proximal portion further comprises one or more positioner controls for selectively extending and retracting the extendable positioners.
7. The catheter of claim 5, wherein the implant holding section comprises an expandable balloon configured to be expanded from a first delivery diameter to a second deployment diameter, and wherein the catheter proximal portion comprises a valve deployment control configured to control expansion of the expandable balloon from the first delivery diameter to the second deployment diameter, wherein the catheter proximal portion further comprises one or more positioner controls for selectively extending and retracting the extendable positioner.
8. A system for replacing a deficient heart valve, comprising: a prosthetic heart valve comprising a radially expandable support stent and one or more valve leaflets, wherein the prosthetic heart valve is configured to be radially expanded from a

delivery diameter to a deployed diameter; and a catheter comprising a catheter proximal portion ending in a catheter proximal end, the catheter further comprising a catheter distal portion ending in a catheter distal end, the catheter having an overall length extending from catheter proximal end to the catheter distal end, wherein the prosthetic heart valve is positioned on the catheter distal portion, the catheter further comprising a plurality of retractable members positioned on the catheter distal portion, each retractable member comprising a member fixed end secured to the catheter distal portion at a position adjacent the prosthetic heart valve, each retractable member further comprising a retractable member free end positioned at a distance longitudinally displaced with respect to the catheter distal portion such that the retractable member extends at least partially over the prosthetic heart valve, wherein each retractable member has a first position wherein the retractable member free end is positioned radially adjacent the catheter distal portion and the retractable member is generally lengthwise and parallel to the catheter distal portion, and wherein each retractable member has a second position wherein the retractable member free end is radially displaced away from the catheter distal portion such that the retractable member is generally non-parallel with the catheter distal portion, and wherein in the second position the retractable member free end is not secured to or contacting any structure other than the retractable member itself, wherein in the second position a portion of the retractable member extends longitudinally over but radially displaced away from and outwardly of the prosthetic heart valve; wherein the prosthetic heart valve is configured to be radially expanded and released from the catheter, and the retractable member is adapted such that after the prosthetic heart valve is released from the catheter the entirety of the retractable member including the retractable member free end and the portion which extends longitudinally over but radially displaced away from the prosthetic heart valve in the second position, remains secured to the catheter and is adapted to be withdrawn with the catheter from the body and away from the released prosthetic heart valve without disrupting the deployed prosthetic heart valve.

9. The system of claim 8, wherein the radially expandable support stent of the prosthetic heart valve is a self-expanding structure comprising a memory material, wherein the

radially expandable support stent is configured to be biased to expand from an unexpanded delivery diameter to an expanded deployed diameter, wherein the catheter further comprises a sheath over at least part of the catheter distal portion, wherein the prosthetic heart valve is positioned on the catheter distal portion at a position at least partially underneath the sheath, and the retractable member in the first position extends at least partially over the sheath.

10. The system of claim 8, wherein the radially expandable support stent of the prosthetic heart valve comprises a generally rigid structure, wherein the radially expandable support stent is configured to be plastically and radially expanded from an unexpanded delivery diameter to an expanded deployed diameter via application of a radial expansion force, wherein the catheter further comprises an expandable balloon positioned on the catheter distal portion, wherein the prosthetic heart valve is positioned on the catheter distal portion at a position at least partially over the expandable balloon, and the retractable member in the first position extends at least partially over the expandable balloon.
11. The system of claim 8, wherein the retractable member fixed end is secured to the catheter at a position proximal of the prosthetic heart valve.
12. The system of claim 8, wherein the retractable member fixed end is secured to the catheter at a position distal of the prosthetic heart valve.
13. The system of claim 8, wherein the retractable member is biased toward the second position.
14. The system of claim 8, wherein the retractable member free end comprises a radiopaque marker having a radiopaque density greater than an average radiopaque density of the rest of the retractable member.
15. A device for delivering a prosthetic heart valve to a position within a patient, comprising: a device proximal portion ending in a device proximal end, the device proximal portion comprising a device handle; a device distal portion ending in a device distal end, the device distal portion having an implant holding section

configured to receive a medical implant thereon; the prosthetic heart valve releasably positioned on the implant holding section, the prosthetic heart valve comprising a valve portion and a support portion; a device usable length from a distal end of the device handle to the device distal end, wherein the device usable length is sufficient to reach from a position outside of a patient's body to a position within a native valve annulus within the patient's body; and at least one extendable positioner configured to be selectively and radially extended from a first position to a second position, wherein in the first position the extendable positioner is positioned generally parallel to and against the device distal portion and longitudinally over at least a portion of the prosthetic heart valve and implant holding section, wherein in the second position at least a portion of the extendable positioner extends radially away from the device distal portion and radially away from and outside of the prosthetic heart valve and outside of all other structures at or secured to the distal portion of the device while extending longitudinally over at least a portion of the prosthetic heart valve, wherein the entirety of the retractable member is configured to remain secured to the device distal portion and to be withdrawn from the body and away from the prosthetic heart valve with the device distal portion after release and deployment of the prosthetic heart valve within the native valve annulus within the patient's body.

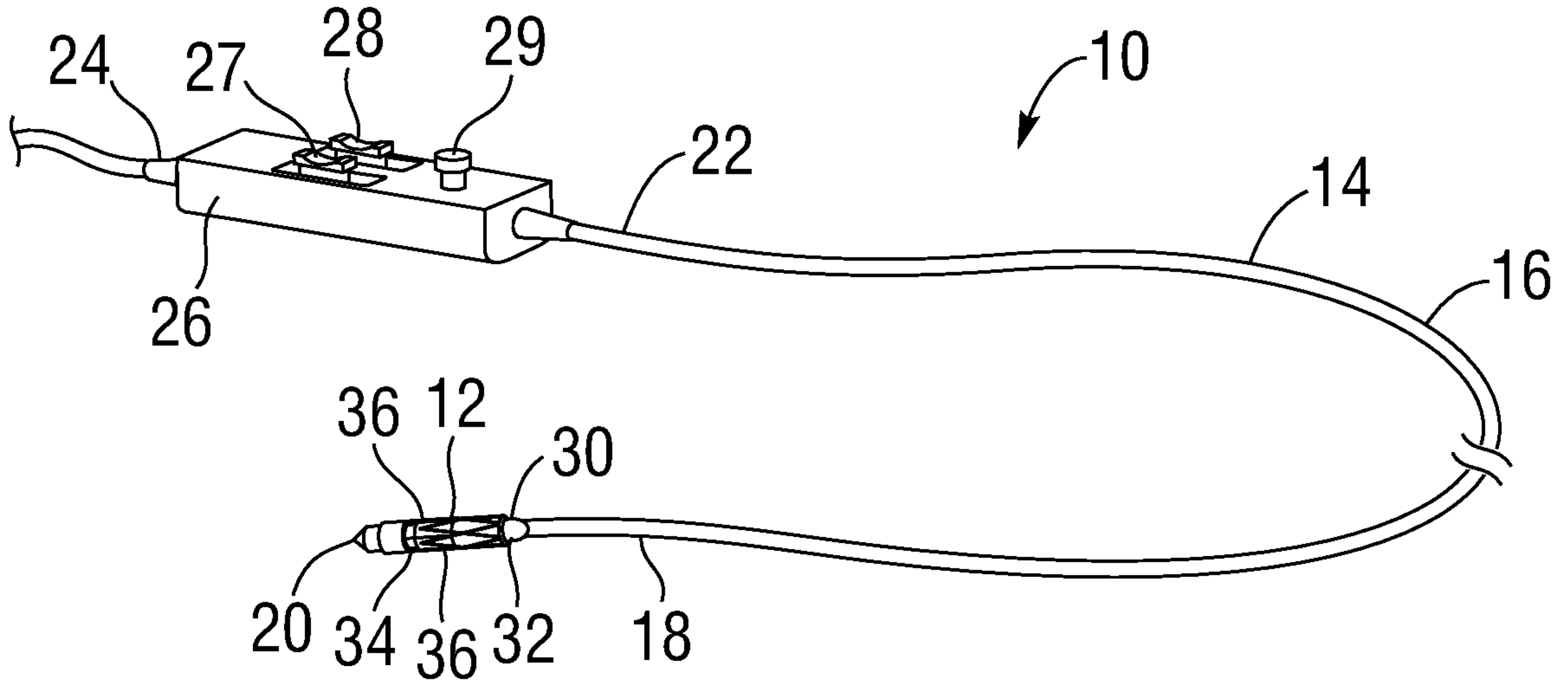
16. The device of claim 15, wherein the extendable positioner extends at least partially over the implant holding section.
17. The device of claim 16, wherein the extendable positioner comprises a positioner fixed end secured to the device distal portion, and a positioner free end configured to be selectively and radially extended away from the device distal portion.
18. The device of claim 17, wherein the positioner free end is positioned along the length of the device at a position distal of the positioner fixed end with respect to the length of the device.
19. The device of claim 17, wherein the positioner free end is positioned along the length of the device at a position proximal of the positioner fixed end with respect to the length of the device.

20. The device of claim 15, wherein at least one extendable positioner is configured to be selectively and longitudinally displaced from a targeting position adjacent the implant holding section to a deployment position longitudinally removed from the implant holding section.
21. The device of claim 15, wherein the extendable positioner comprises a positioner fixed end secured to the device distal portion and a positioner free end, wherein in the first position the positioner fixed end is secured to and adjacent the device distal portion while the positioner free end is radially adjacent the device distal portion, wherein in the second position the positioner fixed end is secured to and adjacent the device distal portion while the positioner free end is extended radially away from the device distal portion.
22. The device of claim 21, wherein in the second position the positioner free end is positioned longitudinally aligned with a middle third portion of the implant holding section.
23. The device of claim 22, wherein the device distal portion comprises a sheath positioned over the implant holding section, wherein the sheath is configured to be slidably retracted from the implant holding section, and wherein the device proximal portion comprises a valve deployment control configured to selectively and slidably retract the sheath from the implant holding section, wherein the device proximal portion further comprises one or more positioner controls for selectively extending and retracting the extendable positioner.
24. The device of claim 22, wherein the implant holding section comprises an expandable balloon configured to be expanded from a first delivery diameter to a second deployment diameter, and wherein the device proximal portion comprises a valve deployment control configured to control expansion of the expandable balloon from the first delivery diameter to the second deployment diameter, wherein the device proximal portion further comprises one or more positioner controls for selectively extending and retracting the extendable positioner.

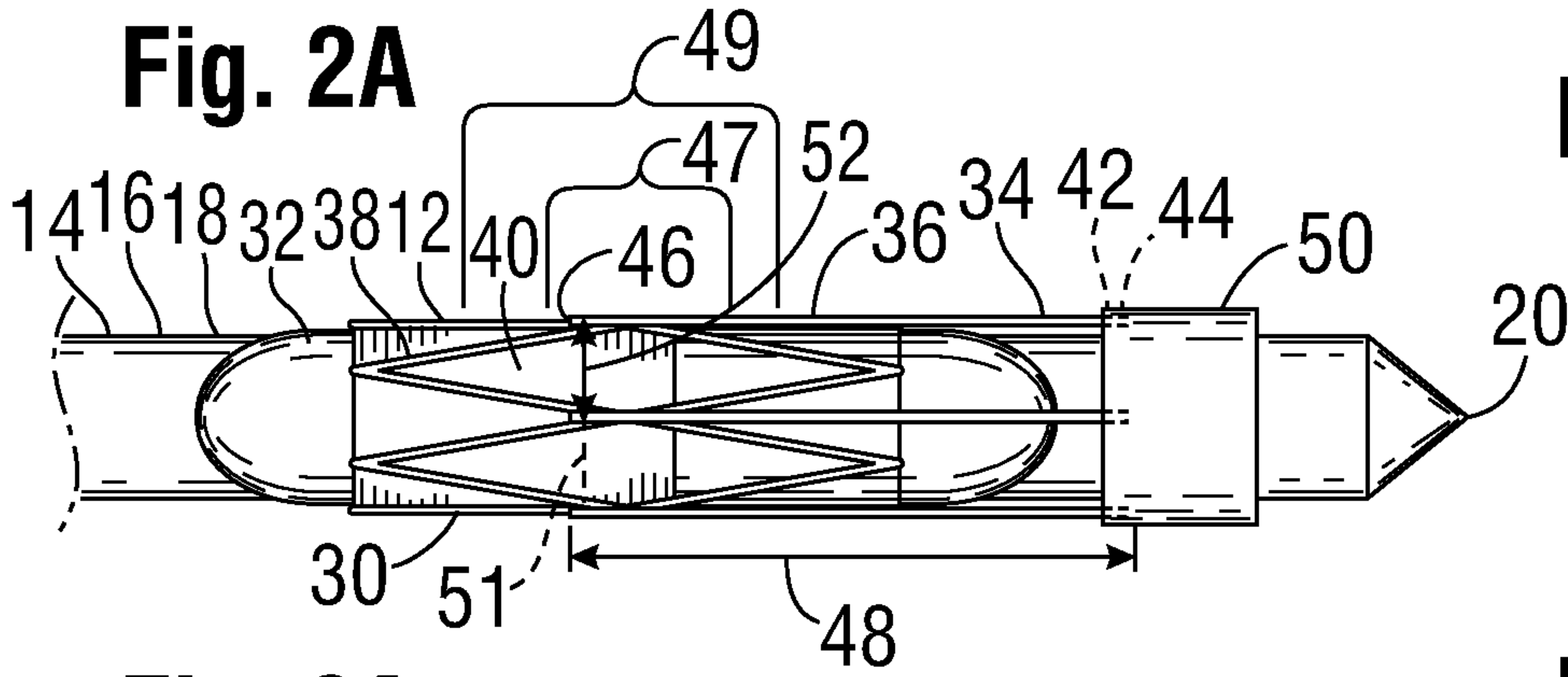
25. The device of claim 15, wherein the device distal portion comprises a radial center, and wherein in the first position the positioner free end is positioned radially away from the radial center by a radial distance of about 2 to 5 mm.
26. The device of claim 15, wherein the device distal portion comprises a radial center, and wherein in the second position the positioner free end is positioned radially away from the radial center by a distance of about 7 to 18 mm.

**Fig. 1**

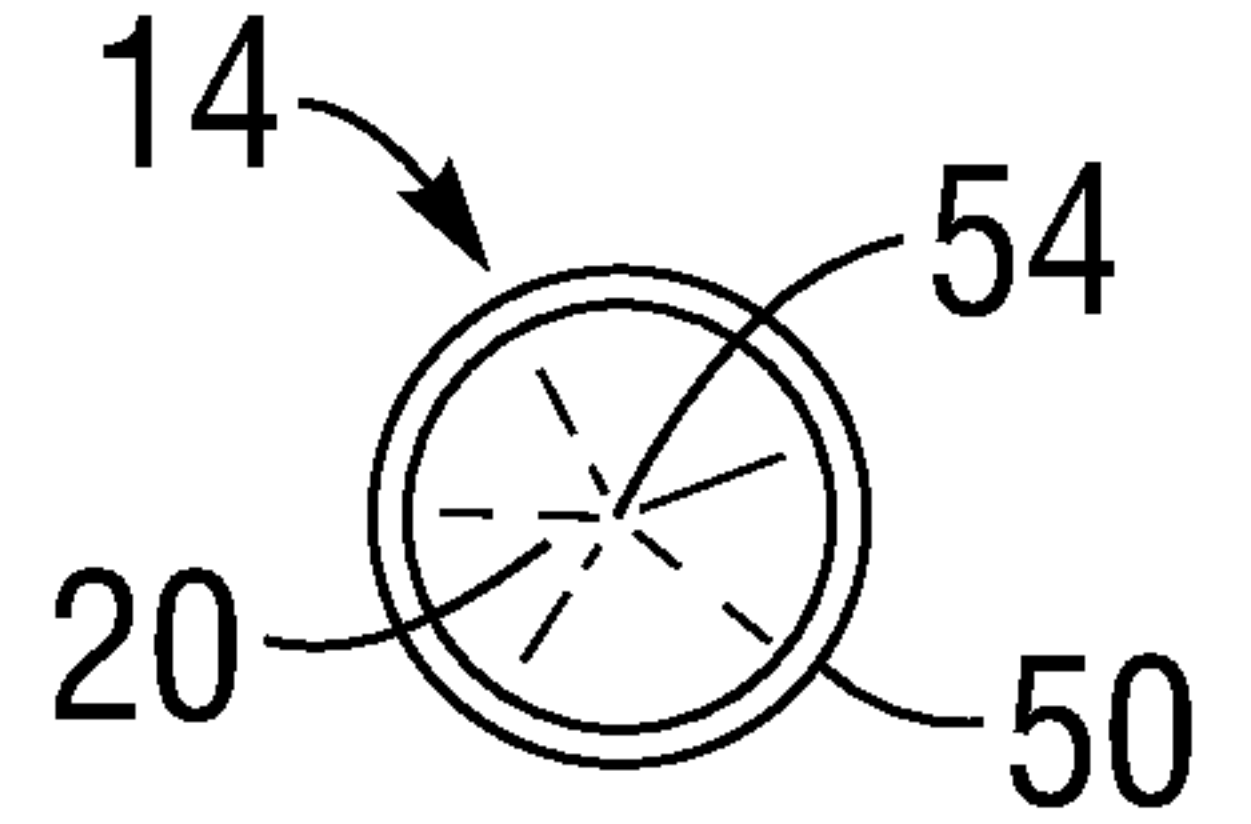
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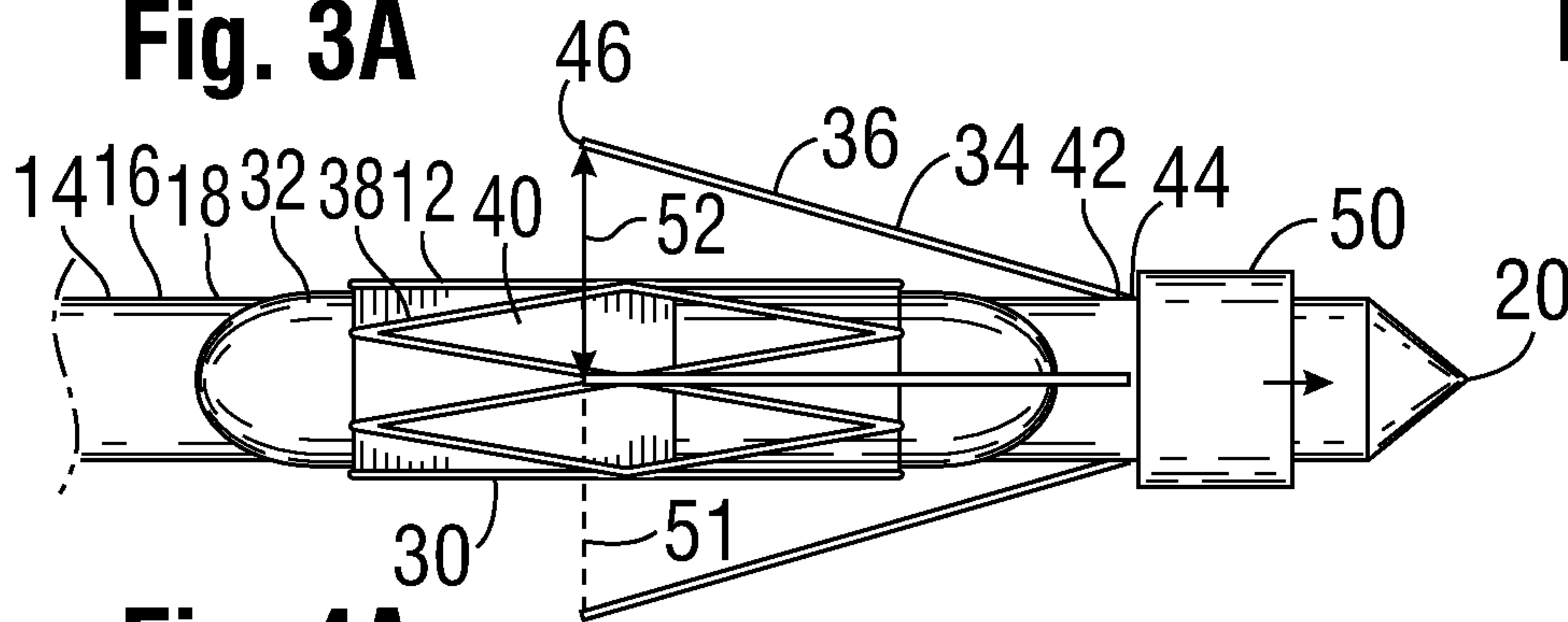
**Fig. 2A**



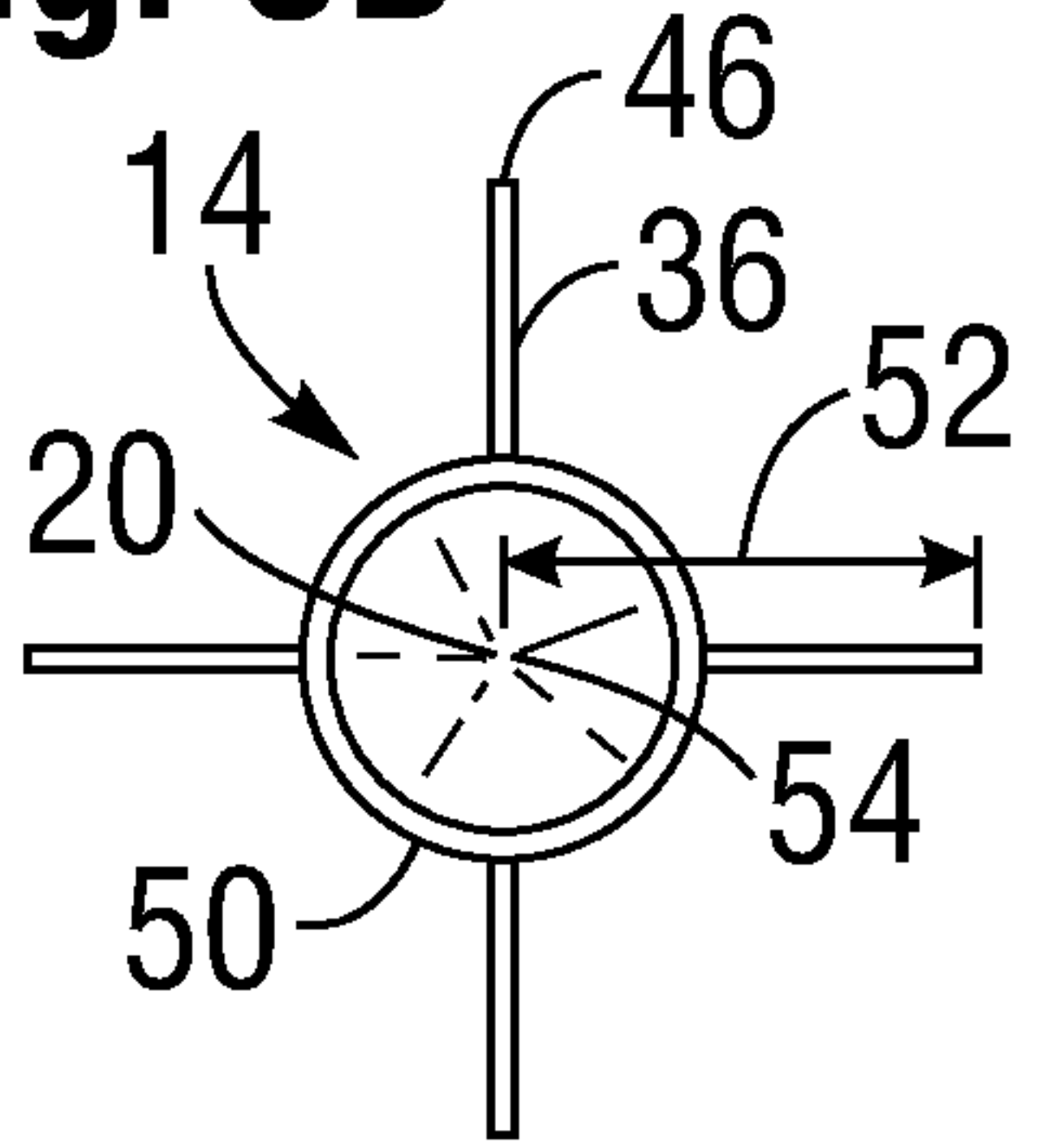
**Fig. 2B**



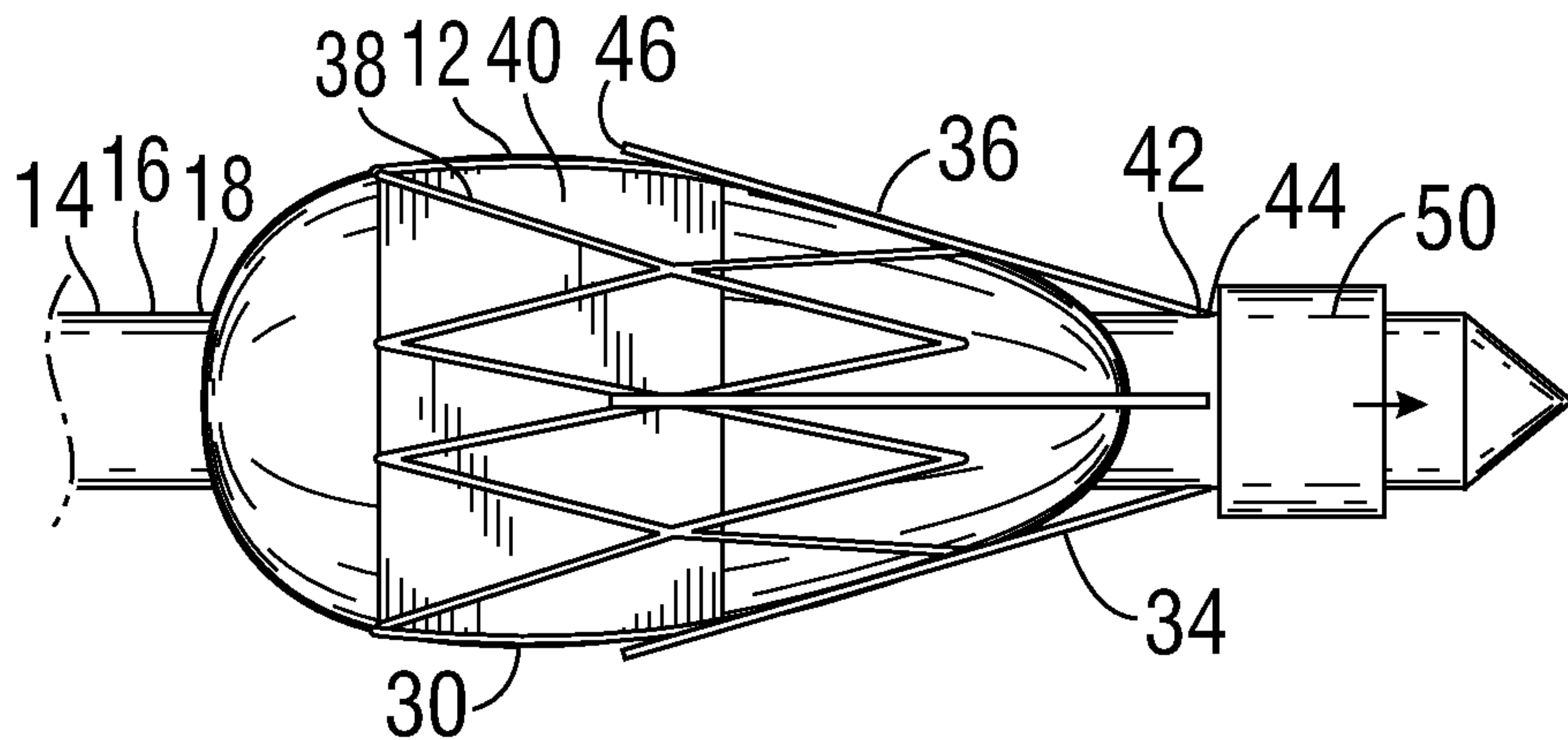
**Fig. 3A**



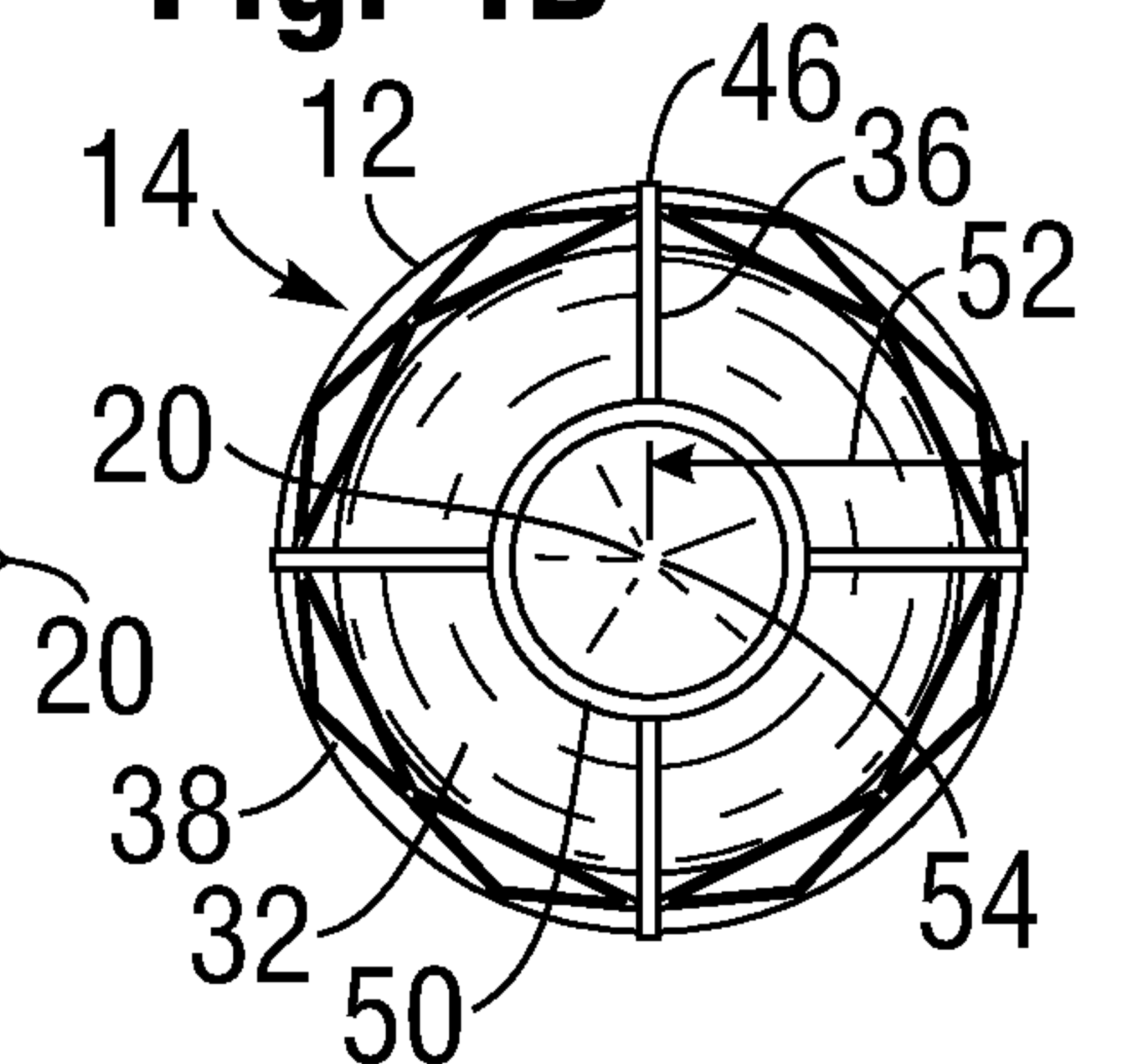
**Fig. 3B**



**Fig. 4A**

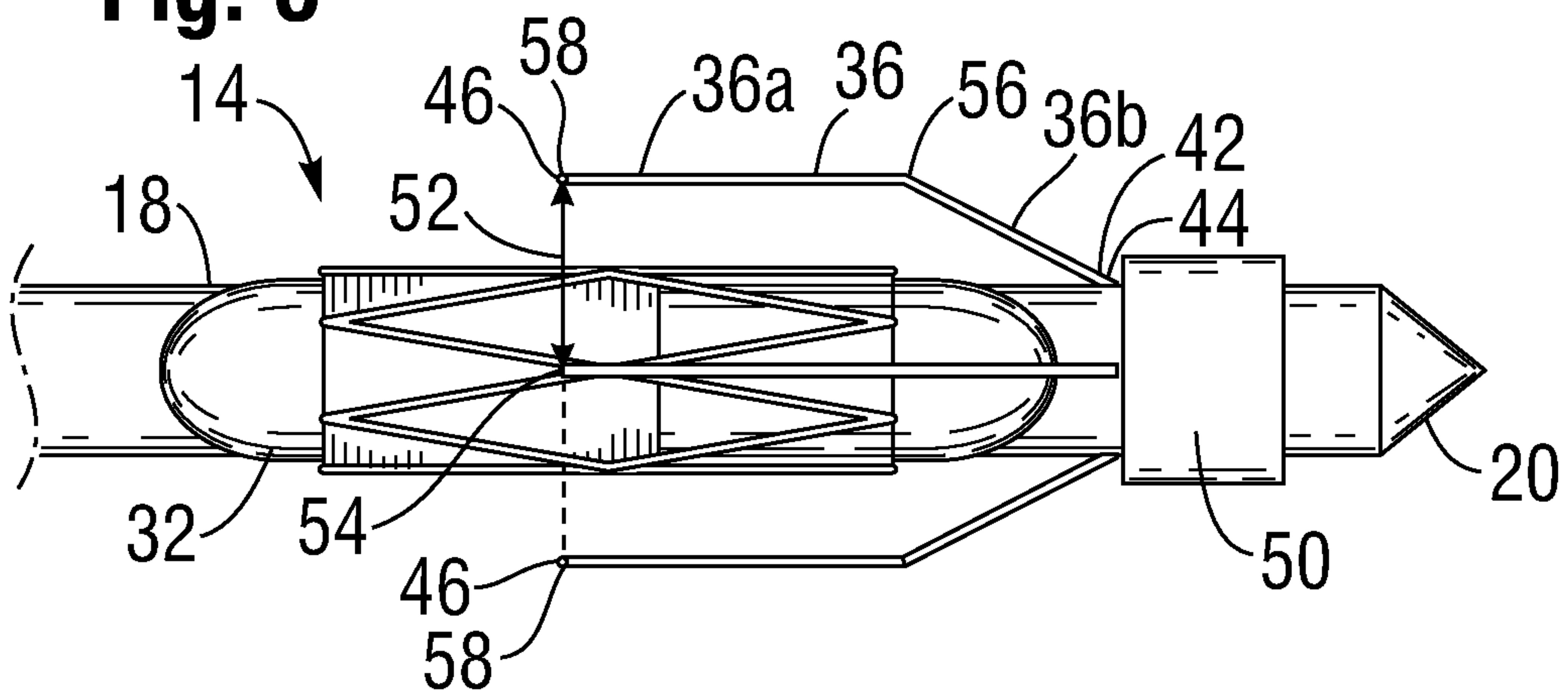


**Fig. 4B**

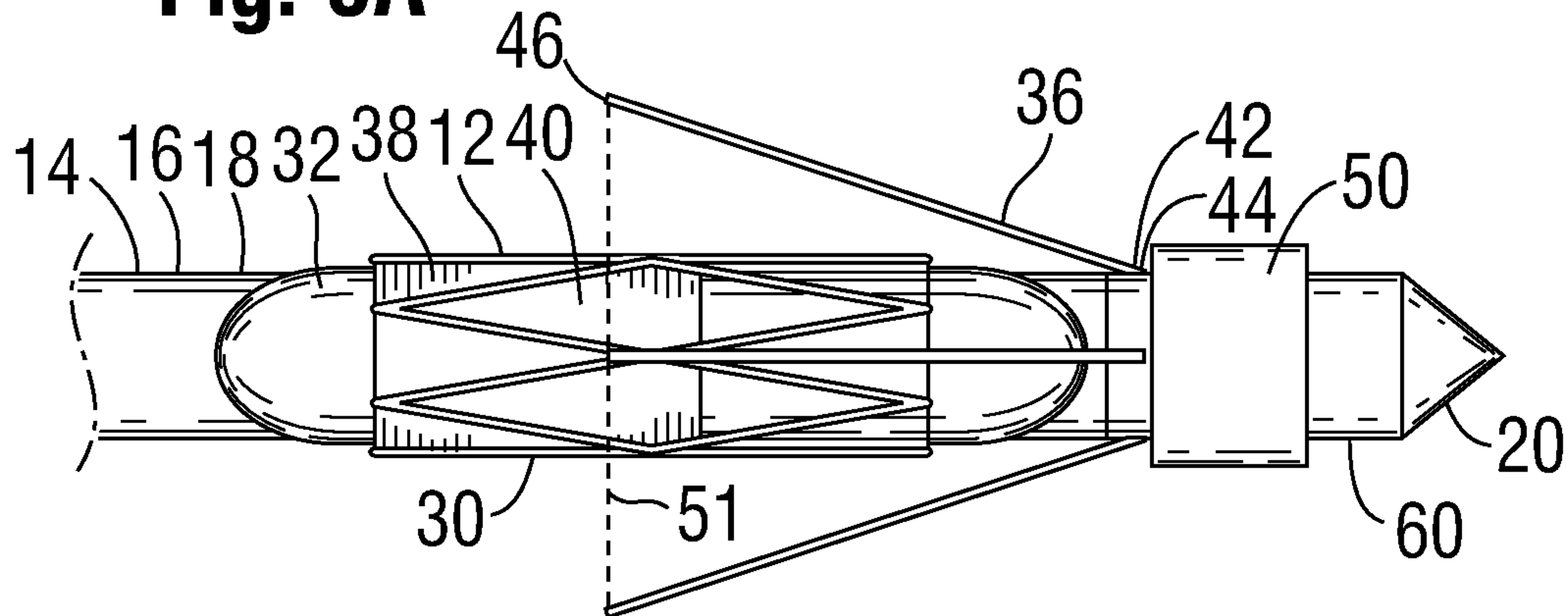


**Fig. 5**

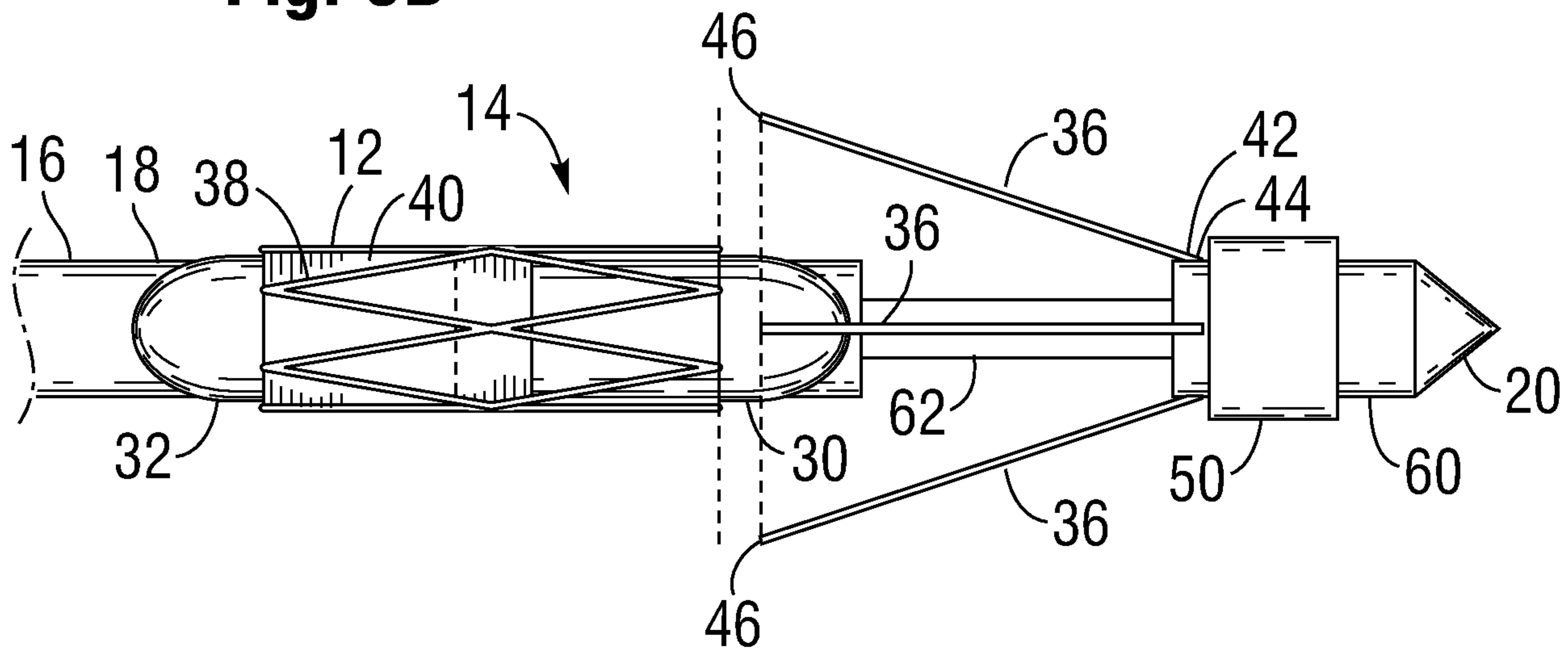
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**Fig. 6A**



**Fig. 6B**



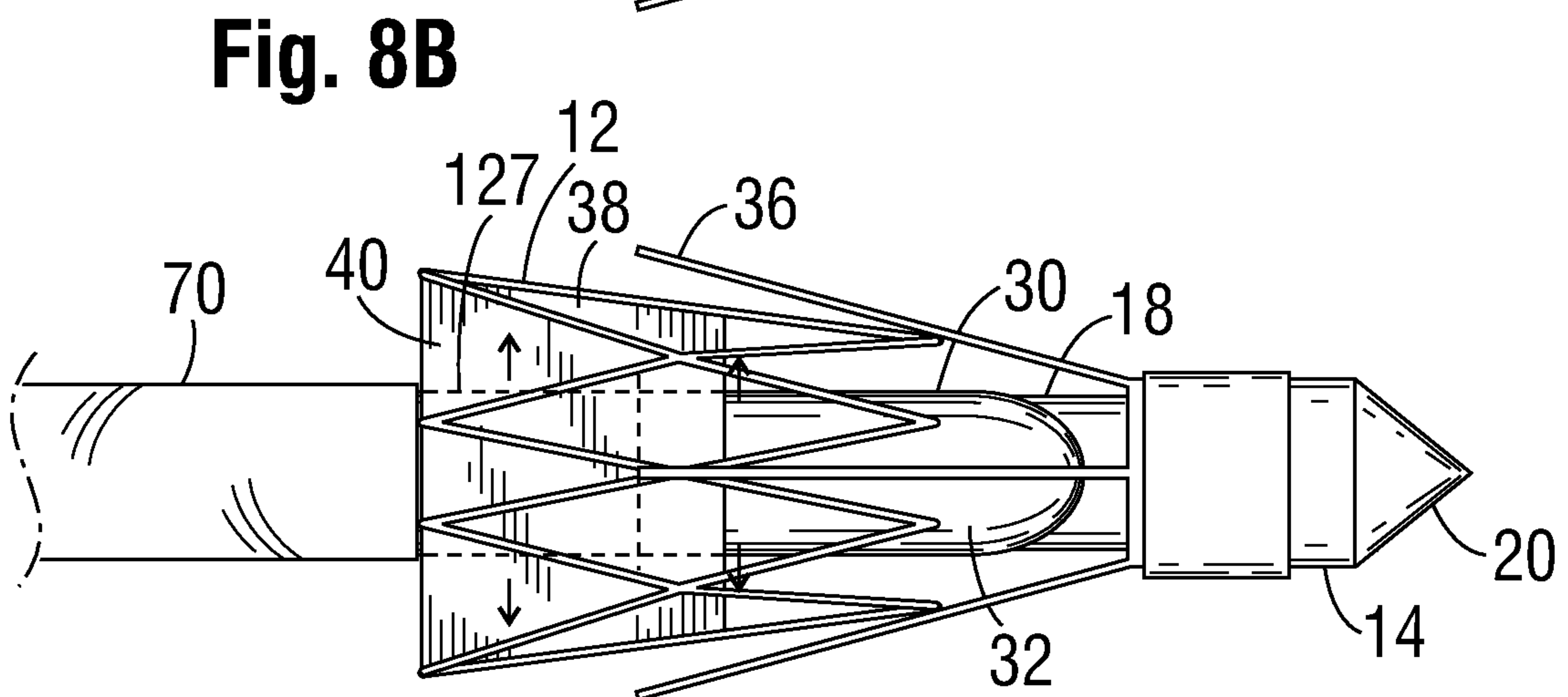
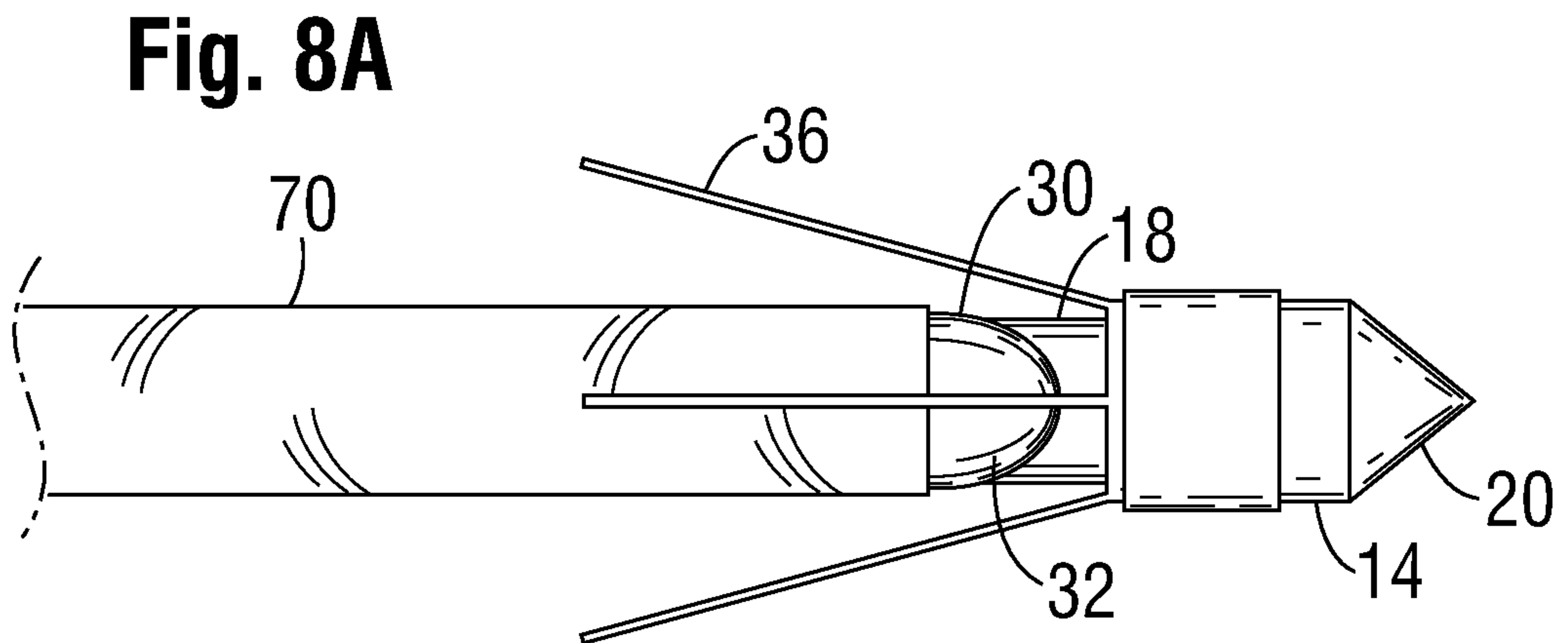
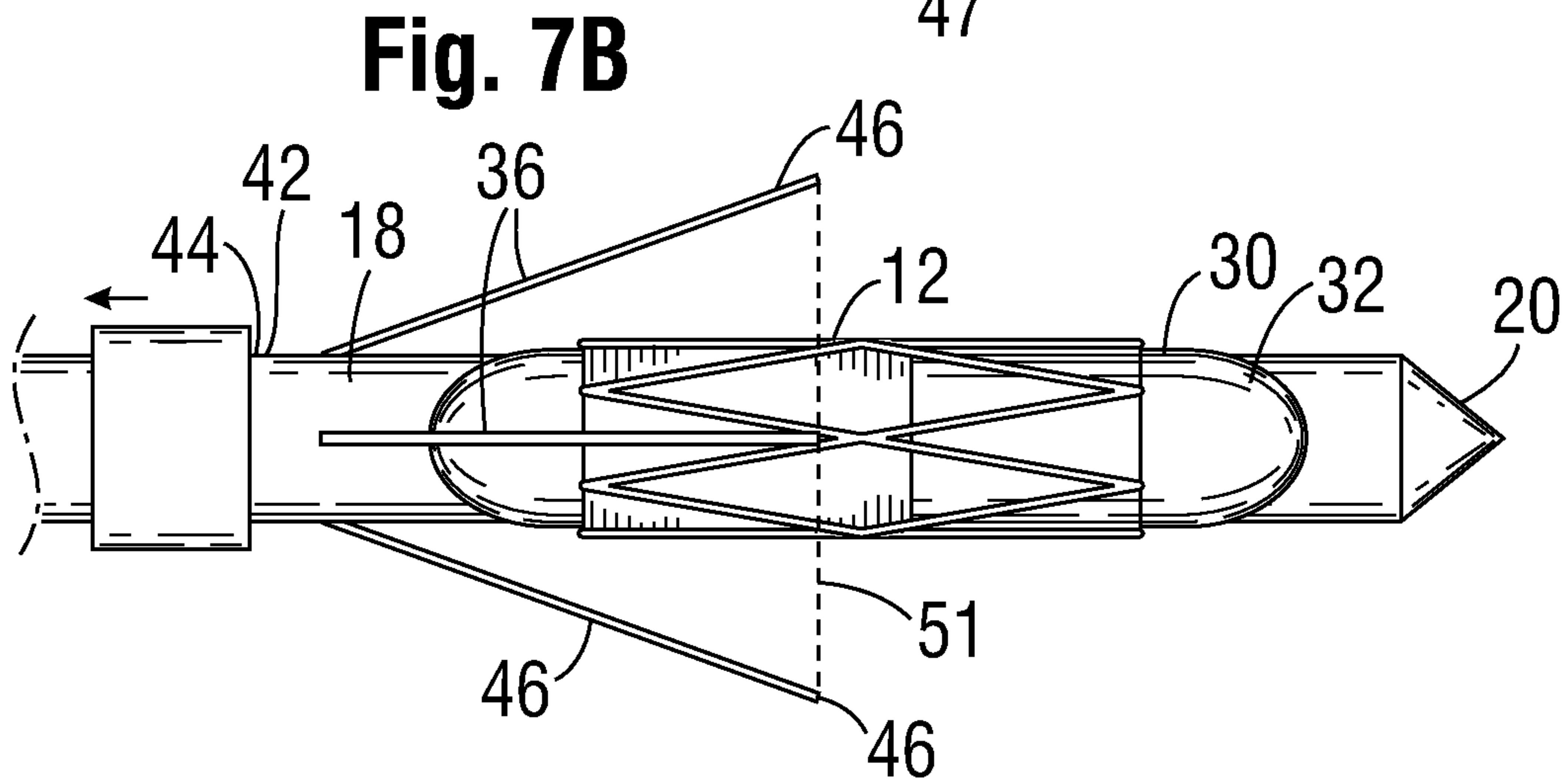
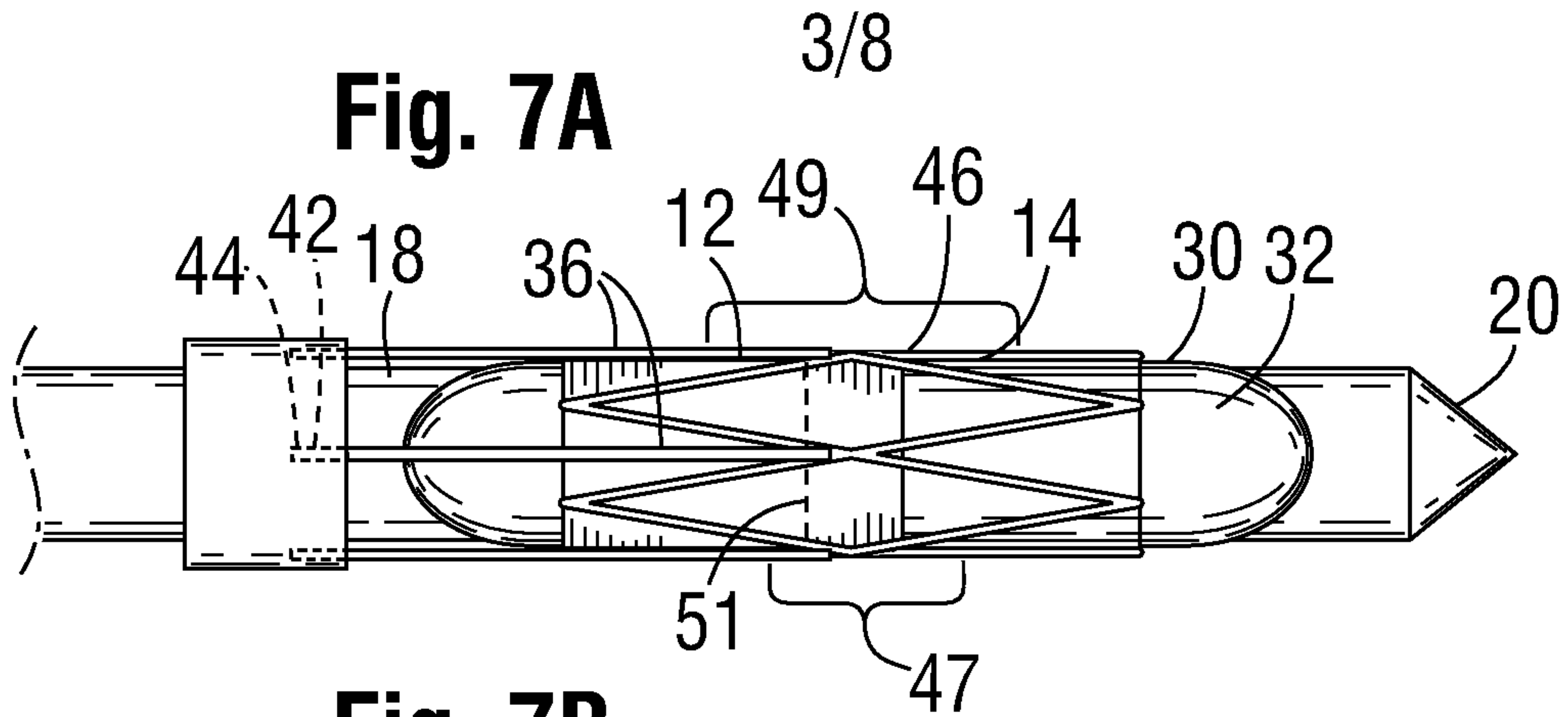


FIG. 9B

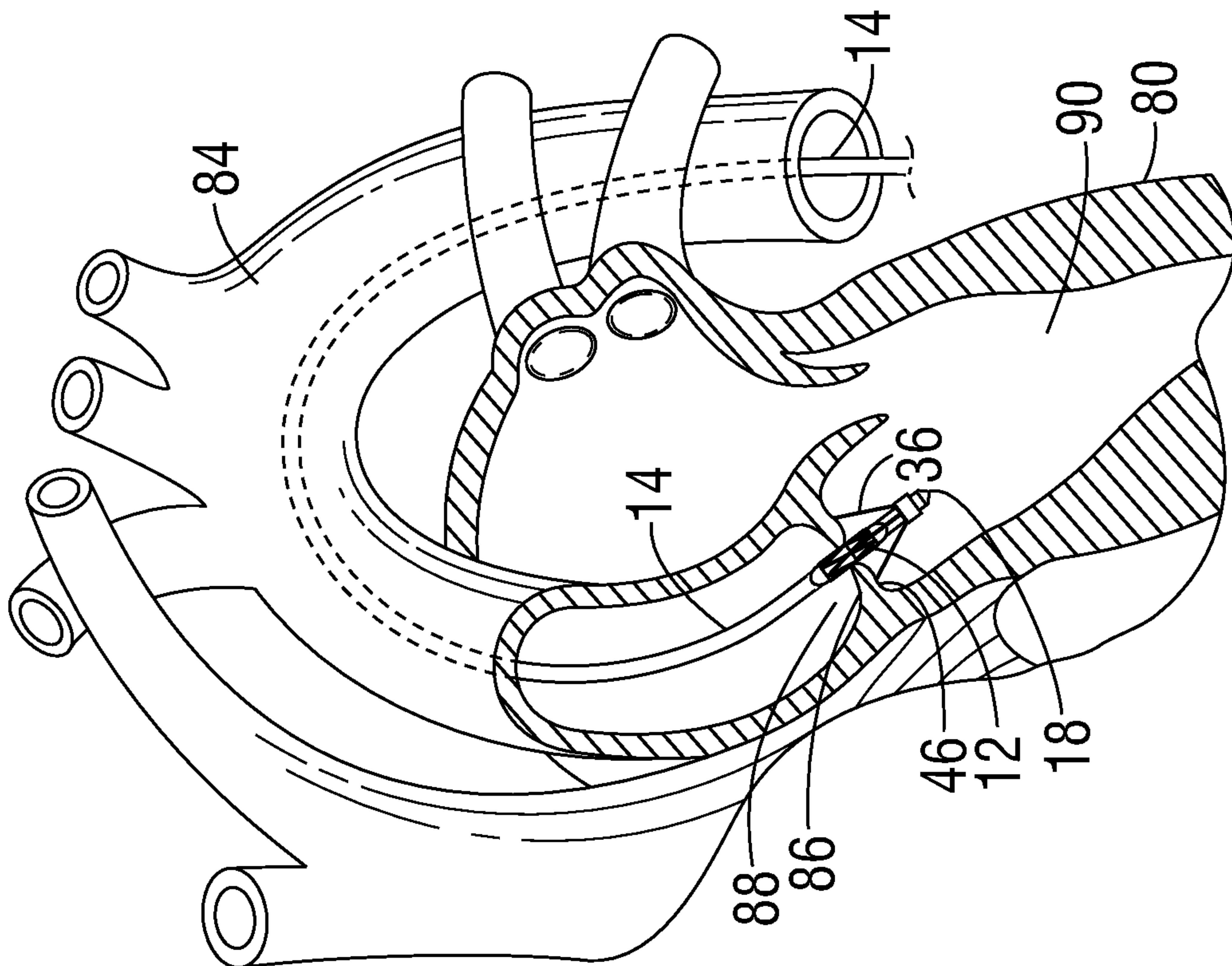


FIG. 9A

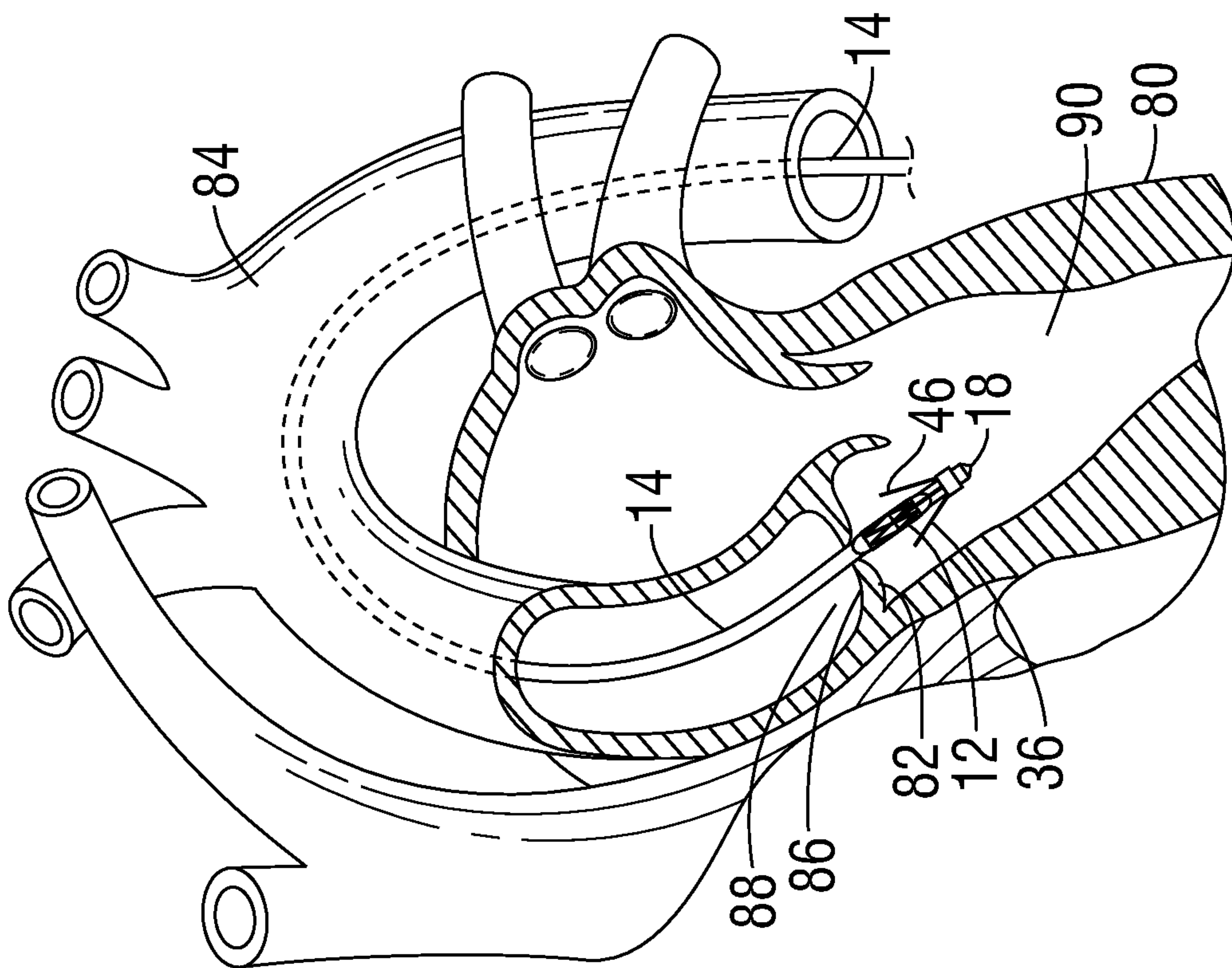


FIG. 10B

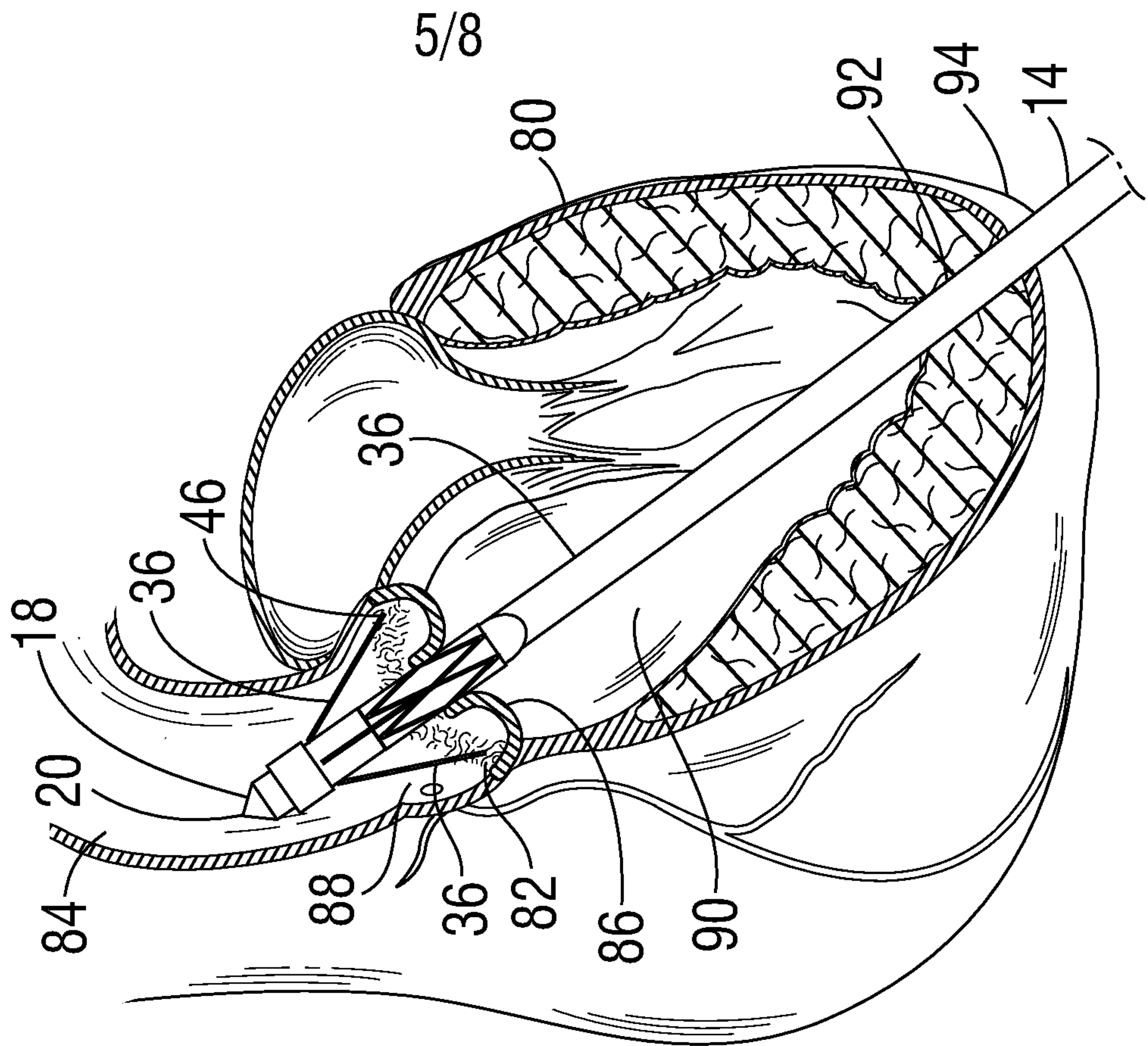


FIG. 10A

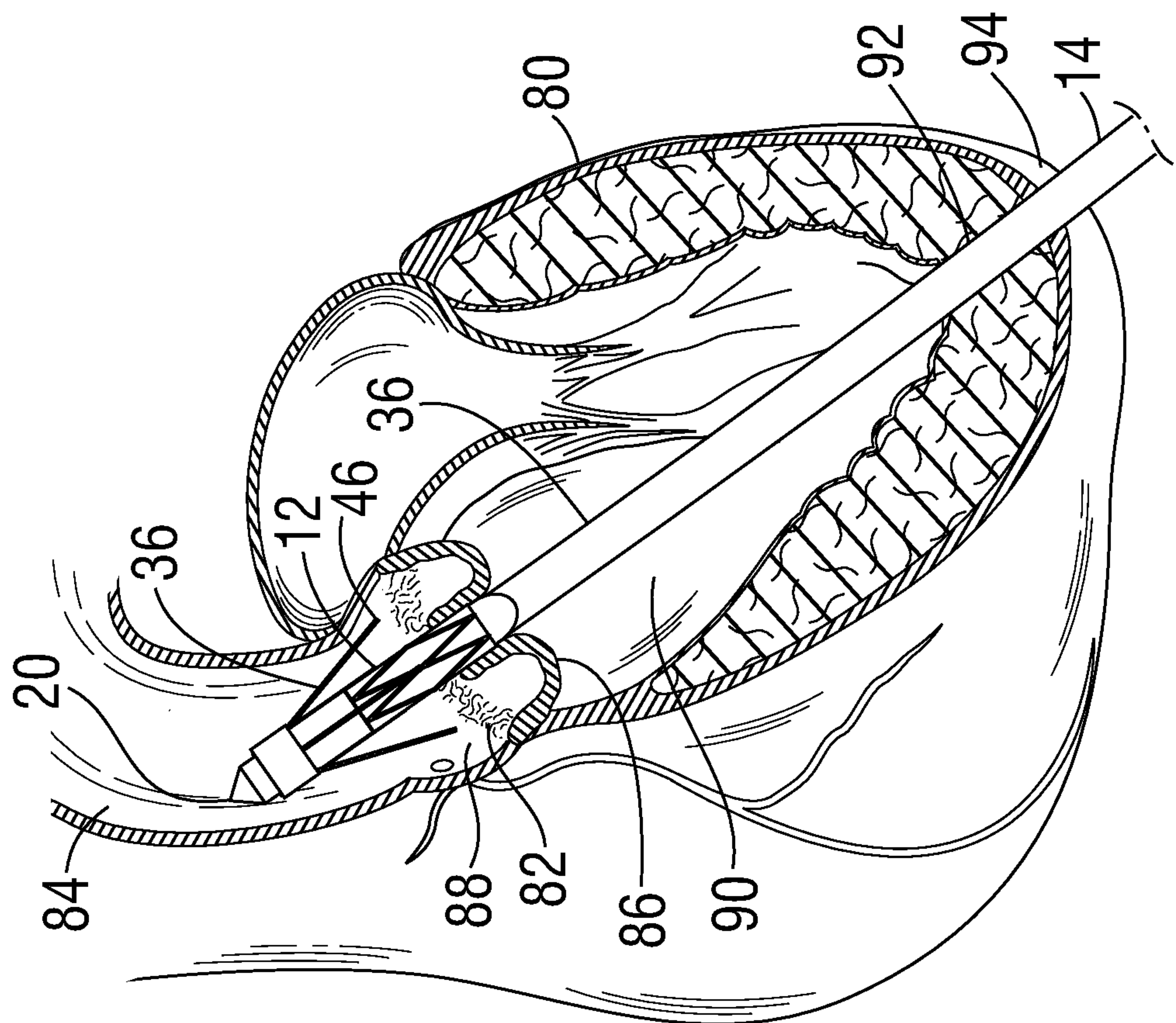


FIG. 11B

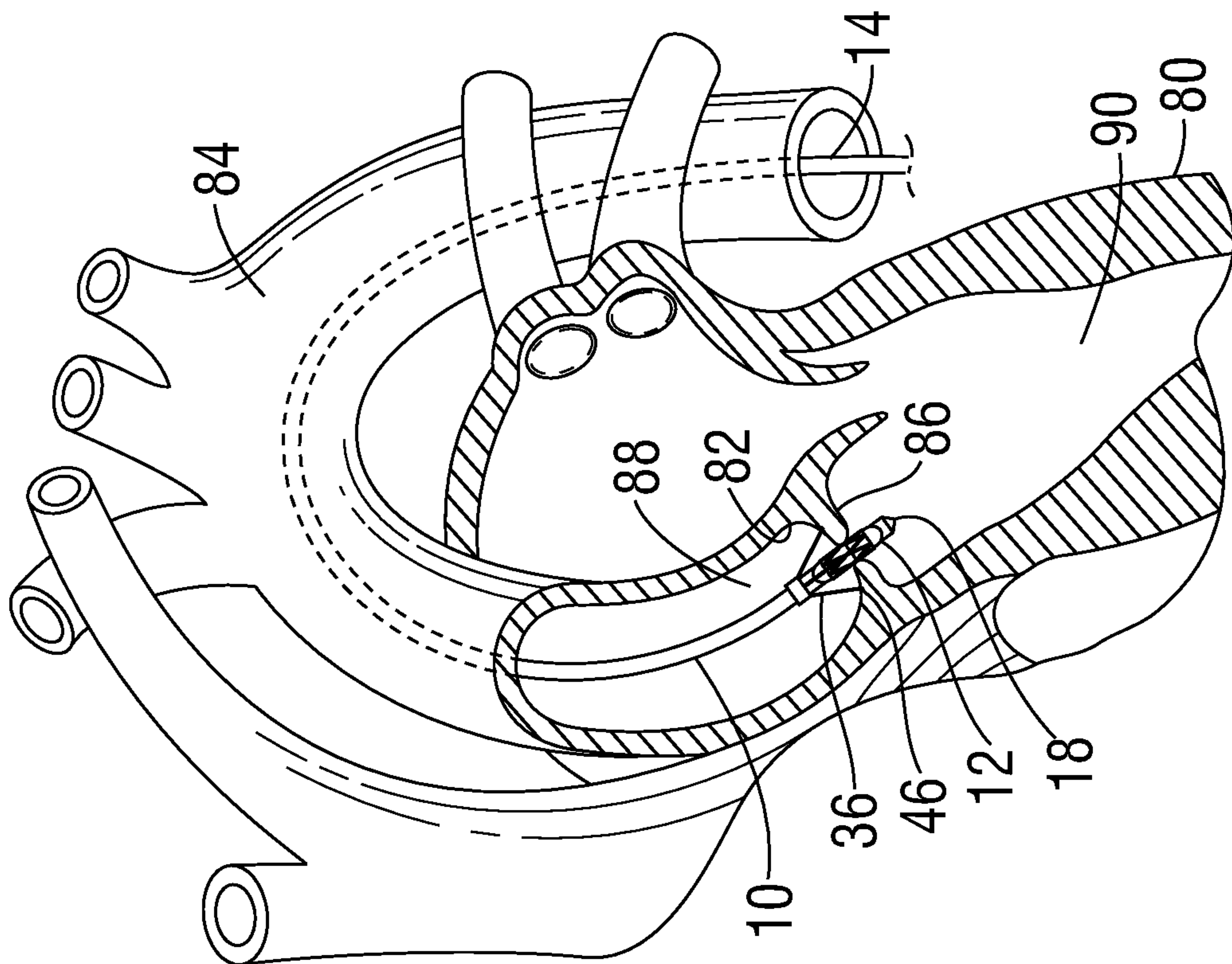


FIG. 11A

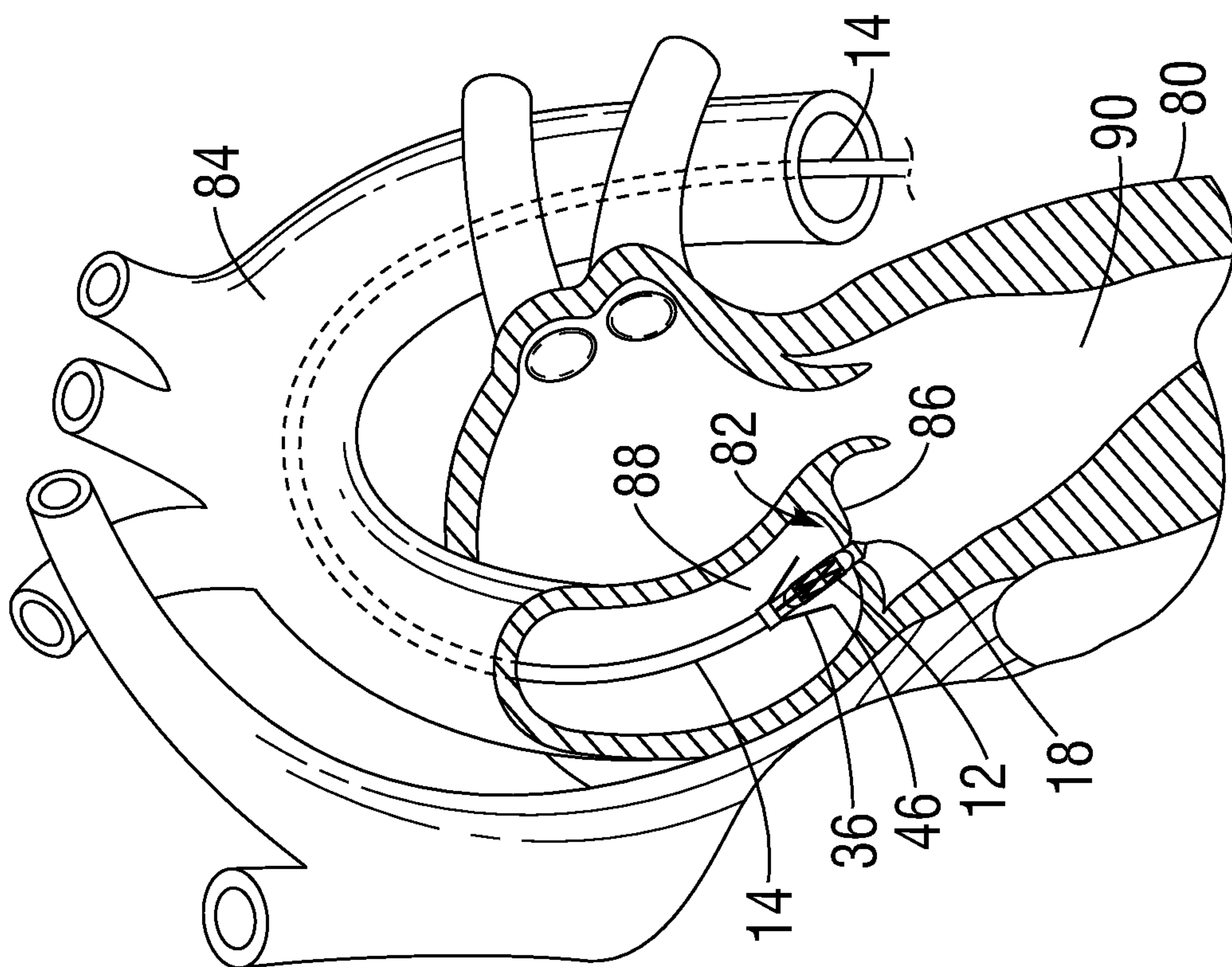


FIG. 12B

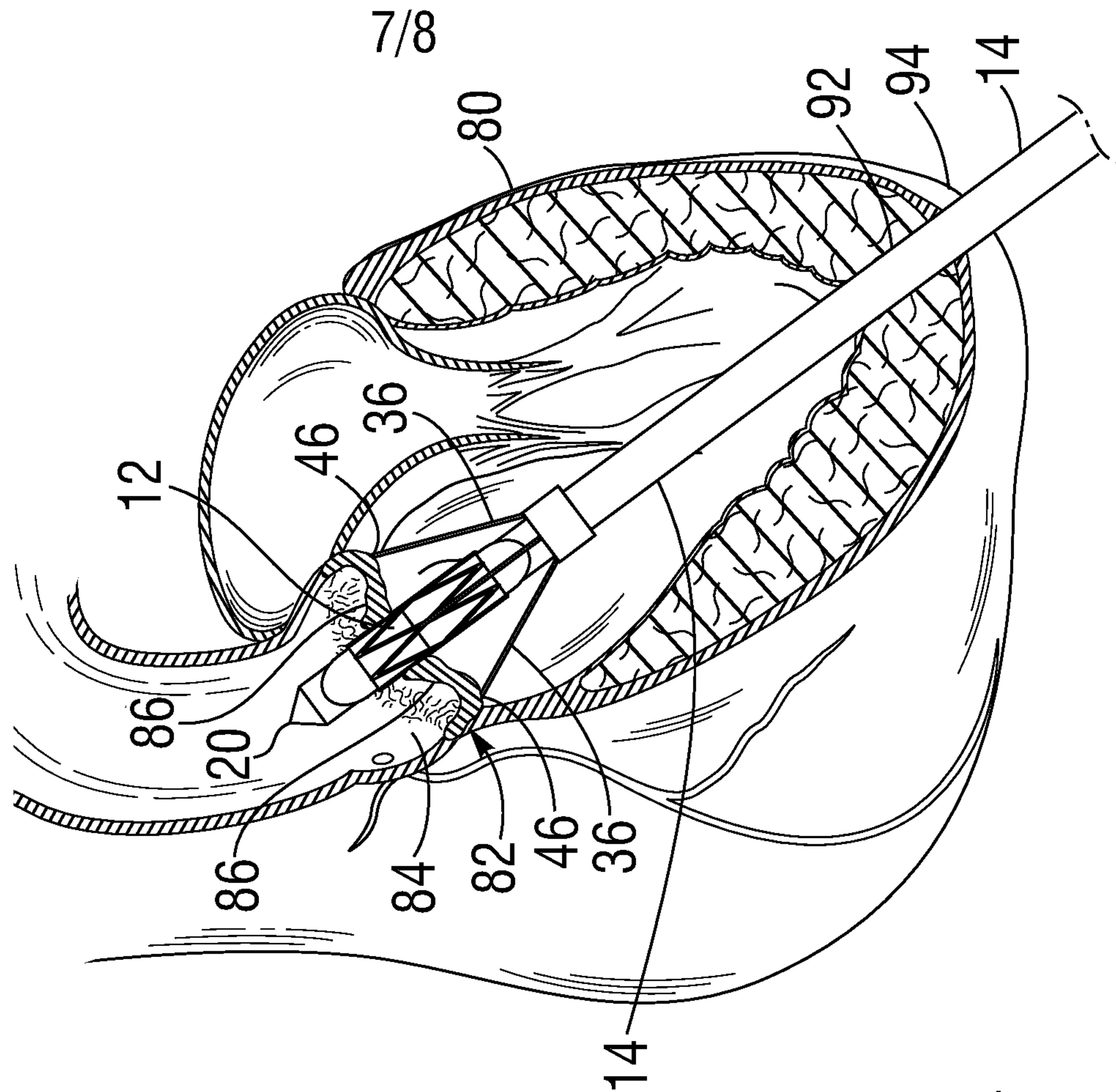
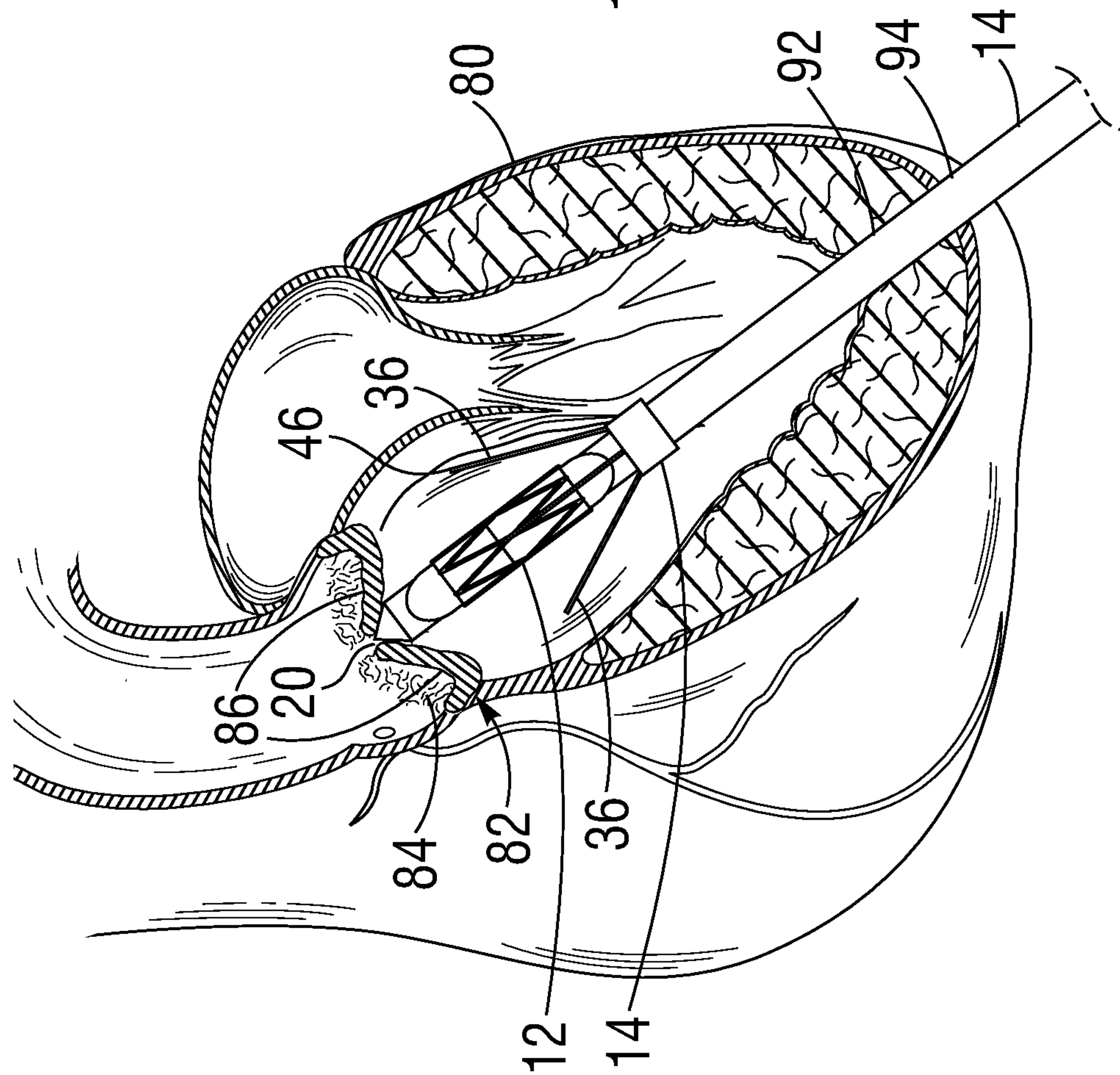
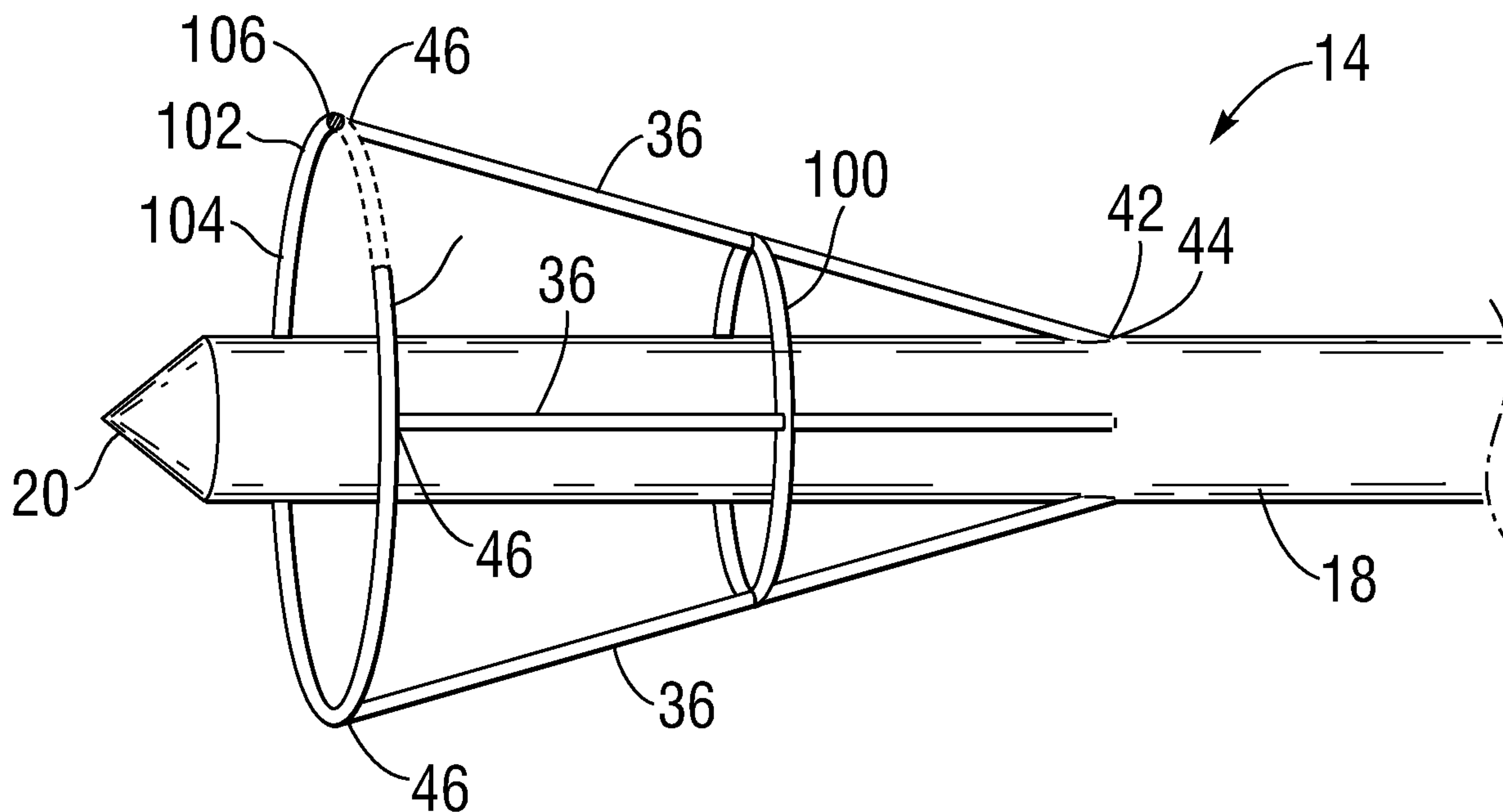


FIG. 12A



**Fig. 13A**



**Fig. 13B**

